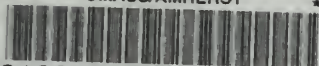


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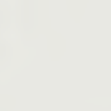
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Number 10 July 1998

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Welcome to
the tenth
issue
of *Healthpoint*.

10

This is the *tenth* edition of a quarterly publication combining both the data and analytic resources of the Massachusetts Division of Health Care Finance and Policy (DHCFP). Each *Healthpoint* updates trends of general interest and presents a treatment of a health policy issue of current importance to policy makers in the Commonwealth. Past issues have covered home health, hospital mergers and mandated benefits. To obtain copies of back issues or to share your comments and suggestions for future policy topics, please contact the DHCFP Office of Communications: (617) 988-3125.

Healthpoint

Information from the Division of Health Care Finance and Policy

MASSACHUSETTS HOSPITALS

UNDER THE BALANCED BUDGET ACT OF 1997

As its name implies, the Balanced Budget Act of 1997 (BBA)

was designed to bring the US government closer to its goal of eliminating the federal deficit. Over three-quarters of the total projected five-year savings of \$127 billion is to be achieved through reductions in Medicare spending. In turn, approximately 30% of the Medicare savings is to be accomplished through reductions in payments to acute care hospitals.¹ In Massachusetts, the Medicare provisions in the BBA are expected to reduce hospital revenue by \$1.4 billion over the next five years. Since Medicare is the single largest purchaser of hospital services, reductions of this size carry important implications for the financial stability of the Massachusetts hospital industry.² This issue of *Healthpoint* assesses the impact of the Medicare provisions in the BBA on acute care hospitals in Massachusetts over the next five years. Special attention is given to the contrasting ability of large teaching hospitals and small community hospitals to absorb the rate reductions.³

Historical Context

The BBA is expected to reduce the annual growth rate in national Medicare spending from the current 8.5% to about 6% by the year 2007. However, Medicare payments to hospitals in Massachusetts have increased at a much slower rate than the national average. In recent years, the rate of growth in per patient charges to Medicare has failed to keep pace even with medical inflation. Since 1993, per patient Medicare charges have risen on average only 1.7% annually, more than one percentage point below the average annual rate of medical inflation. The Commonwealth's hospital profit margin (defined as the difference between revenue and costs divided by revenue) for Medicare patients has also historically been below the national average. A recent study by the Health Care Fi-

Massachusetts Hospital Profit Margins
1994-1997

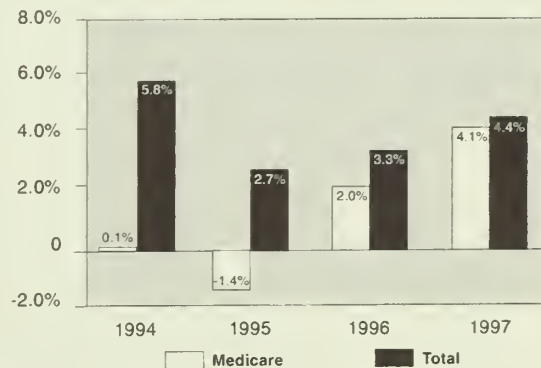


Figure 1

Source: Hospital Cost Reports, Division of Health Care Finance and Policy

nancing Administration (HCFA), the federal agency responsible for administering Medicare, reported that the national Medicare profit margin in 1995 was 10%. State-level data indicate that during the same year Massachusetts hospitals suffered losses of 1.4% on their Medicare admissions (see Figure 1 on page 1). The small and sometimes negative Medicare profit margins have been offset by positive and larger profit margins from private payers. When all payers are counted, Massachusetts hospitals earned profits of 2.7% in 1995, compared to 5.8% nationally.

Hospital financial data reveal three important points for understanding the impact of the BBA cutbacks. First, Medicare payments to Massachusetts hospitals have been declining after adjusting for inflation. Under the terms of the BBA, Massachusetts hospitals can expect further reductions in payments and, therefore, shrinking profit margins net of inflation over the next five years. Second, Massachusetts hospital profit margins are low compared with the rest of the country, providing them less room for adjusting to the rate reductions enacted by the BBA before feeling financially squeezed. Finally, the Massachusetts hospital industry has traditionally been able to absorb low profit margins on its Medicare population by generating higher profits on its private paying patients. A hospital's ability to sustain the BBA cutbacks will depend largely on its share of Medicare patients, and its ability to cross-subsidize these patients by charging higher prices to those who have private insurance—a response that will become increasingly difficult to implement as private payers begin feeling pressure to limit their own expenditure growth.

Medicare Payment Reforms

The BBA reduced the rate of payment for most of the major components of the Medicare hospital reimbursement system. First, the BBA eliminated the hospital base rate update for 1998 and

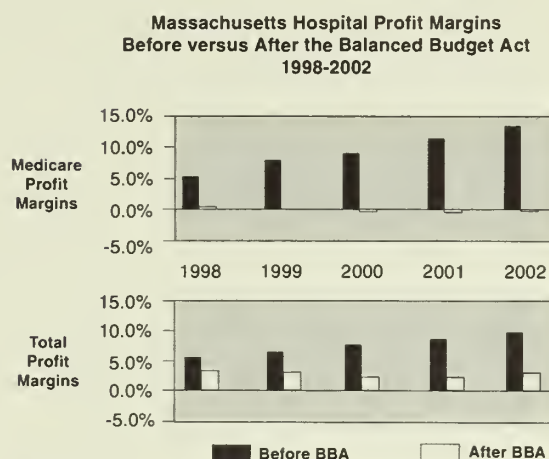


Figure 2

Source: Hospital Cost Reports, Division of Health Care Finance and Policy

fixed it at 1.9 percentage points below HCFA's market basket (MB) in 1999; 1.8 percentage points below MB in 2000; and 1.1 percentage points below MB in 2001 and 2002. Before the BBA, the base rate update (meant to adjust hospital payments for inflation) was scheduled to reflect the full projected change in the market basket. Second, the BBA lowered the rate of payment for capital expenditures permanently by 15.7% and reduced it an additional 2.1% for the next five years. Third, the BBA reduced Medicare reimbursement for uncollected beneficiary co-payments by 45%. Finally, adjustments are made for treating a disproportionate share of poor patients and for providing medical training. Under the BBA, disproportionate share (DSH) and indirect medical education (IME) adjustments were lowered by 5% and 29%, respectively, over the next five years.

Potential Impact of the BBA

The effect of these rate reductions on Massachusetts hospital profit margins is shown in Figure 2 above. The figure compares projected Medicare and total profit margins under payment regulations before versus after the BBA. The results reveal a widening gap between baseline and BBA profit margins. Without the BBA, Medicare profit margins would have been an estimated 6.3% in 1998. Under the BBA, Medicare profit margins are expected to drop to 0.5% in 1998. By the year 2002,

Massachusetts hospitals are expected to suffer losses of 0.1% on Medicare patients under the BBA, compared with a 14.4% Medicare profit under prior regulations. Total profit margins, on the other hand, decline but remain positive following implementation of the BBA. When all patients are included, profit margins fall to an estimated 2.5% during the first year of the BBA. This is three percentage points below projections under prior regulations. Without the policy changes, total profit margins would have risen to almost 10% by the year 2002. Instead, Massachusetts hospitals are expected to earn profits of only 2.3%. The difference between profit margins before and after the BBA represents a cumulative loss of \$1.4 billion over the next five years. This is equivalent to 10% of total hospital revenue between 1998 and 2002.

Community versus Non-Community Hospitals

Hospitals doing well before the payment change will not be seriously threatened by the cutbacks contained in the BBA. However, hospitals struggling to survive prior to these policy reforms will have a more difficult time incorporating the payment reductions. The effects of the payment change will be more onerous on those hospitals with a sizable share of their patient base covered by Medicare. To illustrate the differences in impact, Medicare and total profit margins under the BBA for two hospital groups have been calculated. The first group, referred to as "community hospitals," consists of the 22 smallest hospitals in the state that do not receive IME or DSH payments. The average number of beds for hospitals in this group is 82. The second group, referred to as "non-community hospitals," includes the 23 largest hospitals that receive both IME and DSH payments.

Average hospital size in this group is 339 beds. The average share of Medicare admissions in the community hospital group is 53%, and in the non-community hospital group, 39%.

The Medicare profit margin for non-community hospitals is expected to be 3.7% in 1998, falling to 0.6% by 2002 (see Figure 3 above). In contrast, community hospitals are expected to suffer losses on their Medicare patients of 15.4% during the first year of the BBA and losses of 10.9% in five years. When all payers are included, the predicted profit margin for non-community hospitals is 4.8% in 1998 and 3.4% in 2002. These profits are below what non-community hospitals would have earned under the old regulations, but still within sustainable operating margins, especially since Medicare represents a smaller share of their patient population. Even with private paying patients, however, it will be difficult for community hospitals to adjust to the projected revenue shortfall under the BBA. Community hospitals are expected to incur total losses of 7.7% in 1998 and 5.2% in 2002. The financial well-being of small community hospitals, with a traditionally lower level of profit and a higher share of Medicare patients, will be most threatened by the rate reductions mandated by the BBA.

Future Considerations

Under the BBA, all providers (including hospital outpatient departments, home health agencies, skilled nursing facilities, and chronic, rehabilitation and psychiatric hospitals and units) will be

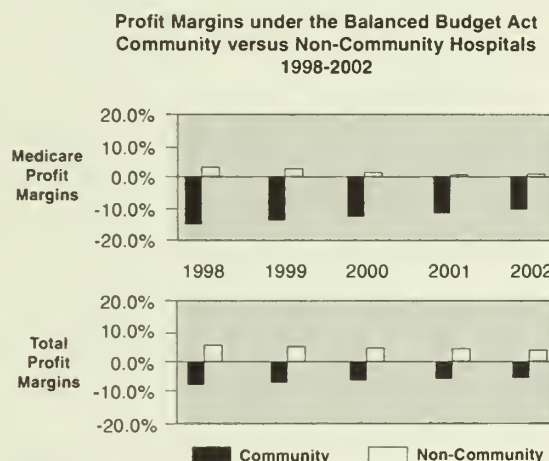


Figure 3

Source: Hospital Cost Reports, Division of Health Care Finance and Policy

switched to prospective payment systems. In addition, the BBA embraces managed care (including HMOs, preferred provider plans, provider-sponsored plans, religious fraternal benefit plans, and medical savings accounts) as a model for providing health care to its beneficiaries. The first of these reforms gives Medicare a mechanism for controlling the growth in federal health care spending. The second gives the private market greater control over the benefits to be provided. As Medicare moves from a benefit program that guarantees patients a set of health benefits to a contribution program that gives beneficiaries a fixed amount of money to purchase their own health care needs, the potential for quality and access problems, as well as for a shift in responsibility to Medicaid, warrants careful monitoring by the state.

Endnotes

1. Acute care hospitals are reimbursed under Medicare's Prospective Payment System (PPS). Chronic rehabilitation, psychiatric and specialty hospitals and units within acute care facilities are exempt from PPS and reimbursed under a cost-based system. There are 85 hospitals in Massachusetts reimbursed under PPS.
2. Medicare pays for over 40% of admissions and accounts for over 50% of hospital revenue in Massachusetts. As the baby boomer generation begins entering its retirement years, Medicare's share of admissions and revenue will continue to increase.
3. The analysis presented in this issue is taken from a report prepared by the Massachusetts Division of Health Care Finance and Policy (DHCFP) for the state legislature. The report analyzes the impact of the BBA on all health care providers, as well as on consumers and Medicaid. Copies of this report, *The Impact of Medicare Provisions in the Balanced Budget Act of 1997 on Massachusetts Health Care Providers, Consumers and Medicaid*, are available by calling the DHCFP Office of Communications at (617) 988-3125.

Further Reading

The Impact of Medicare Provisions in the Balanced Budget Act of 1997 on Massachusetts Health Care Providers, Consumers and Medicaid. DHCFP, May 1998.

Report to Congress: Medicare Payment Policy, Medicare Payment Advisory Commission, Washington, D.C., March 1998.

An Examination of Key Medicare Provisions in the Balanced Budget Act of 1997, Marilyn Moon, Barbara Gage and Alison Evans, The Urban Institute, Washington, DC, September 1997.

Did you know?

Readmissions Cost More

After discharge from a hospital, a patient is sometimes readmitted within a short period of time for a related illness. Many of these readmissions are preventable with good discharge planning, adequate patient education, patient adherence to prescribed regimens and access to adequate outpatient care. Any hospital admission, particularly when it is for a preventable condition in the first place, is costly to the health care system and undesirable for the patient. Data from the Massachusetts Division of Health Care Finance and Policy hospital discharge database show that charges for related, unscheduled readmissions for congestive heart failure are 30% higher on average than for the initial admission. For bacterial pneumonia readmissions, charges are 26% higher on average than for the initial admission. Here are fiscal year 1996 data on initial admissions and related, unscheduled readmissions for congestive heart failure and bacterial pneumonia in Massachusetts acute care hospitals:

	Congestive Heart Failure	Bacterial Pneumonia
Number of Initial Admissions	17,006	17,416
Number of Readmissions	4,024	2,026
Readmission Rate	24%	12%
Initial Admission Average Charge	\$8,312	\$8,826
Readmission Average Charge	\$10,785	\$11,157
Initial Admission Average Length of Stay	5.7 days	6.5 days
Readmission Average Length of Stay	6.7 days	7.4 days

Source: Massachusetts Division of Health Care Finance and Policy, Fiscal Year 1996 Hospital Case Mix and Charge Database.

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HEALTH INSURANCE COVERAGE DECISIONS

The recent media spotlight on coverage of Viagra raises interesting questions regarding how and under what circumstances insurance companies cover new drugs and medical procedures. This issue of *Healthpoint* examines a number of factors affecting coverage decisions made by health insurance companies and self-insured employers in the Commonwealth of Massachusetts.

This analysis focuses on two case studies—human growth hormone (HGH) to treat short stature and autologous bone marrow transplant (ABMT) for breast cancer patients—to illustrate the complexity and competing pressures inherent in making coverage decisions. Specifically, these case studies suggest some of the difficulties in trying to uniformly apply clinical standards, as well as the role of non-clinical factors such as litigation, legislative mandates, cost, and public opinion in coverage decisions.

Making Coverage Decisions

The Division of Health Care Finance and Policy conducted an informal survey to examine the processes Massachusetts insurers and self-insured companies use to make coverage decisions. The National Committee for Quality Assurance (NCQA) requires that accredited managed care organizations (MCOs) adopt a formal process for evaluating when to cover a new health care service, procedure, or pharmacological treatment. However, NCQA does not detail how MCOs should structure this process, resulting in variation among insurers. In order to comply with the NCQA standard, many insurers have developed medical technology committees to analyze clinical, regulatory, legal, ethical, and actuarial issues related to coverage. While these committees draw on the expertise of a range of specialists, few appear to include direct member representation.

Within these formal structures, Massachusetts insurers use a range of analytic tools to make coverage decisions, including cost-benefit and cost-effectiveness analysis, polling, statistical studies, and competitor analysis. One insurer uses cost-effectiveness techniques to “evaluate the added value and cost of a newer therapy compared to a more conventional technology.” Another medical director noted the importance of such techniques because “coverage decisions aren’t black and white; the public doesn’t realize how involved the process of making these decisions needs to be.”

Usually, self-insured employers, whose plans cover nearly half of the 2.7 million Massachusetts HMO subscribers, rely on third party administrators (often MCOs) to

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Number 11 October 1998

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make coverage decisions for them. One employer stated, "the overriding principle is to listen to the expertise of our third party administrator, but not to follow it blindly." A consultant suggested that when self-insured employers diverge from their administrators, it is often because a health issue has been brought to the attention of a company executive through personal experience or staff pressure.

Human Growth Hormone

All of the insurers and employers surveyed cover HGH and ABMT as part of their benefit packages. However, some require providers to obtain prior authorization for the patient before treatment is administered. While some survey respondents have estimated the incremental cost of covering both of these therapies, none quantified these costs for this publication.

Massachusetts insurers use medical necessity as the primary standard for assessing whether to cover a new therapy. Medical necessity implies that a treatment is essential for a patient's physical or mental health, and that treatment complies with generally accepted medical practice. However, an analysis of HGH coverage illustrates the subjective nature of the term "medical necessity" and the limits inherent in applying it to determine coverage.

HGH is prescribed as a standard of care for children for three medical conditions that result in short stature: growth hormone deficiency, Turner syndrome, and chronic renal failure. Physicians also prescribe it for children with non-medical idiopathic (inherited) short stature. Generally, health insurers in Massachusetts cover HGH for the above mentioned medical conditions but not for idiopathic short stature. However, the primary goal of prescribing HGH for these conditions is to increase height, rather than to treat an underlying medical problem. Therefore, covering it even for the specific medical conditions may be difficult to justify on the grounds of medical necessity.

Furthermore, despite the high cost of HGH therapy and the relatively widespread coverage of it for medical conditions, the efficacy of this treatment remains in question. The drug must be injected every day for approximately ten years at a cost of \$14,000-\$30,000 per year. It remains difficult, however, to predict which children will respond to treatment. In fact, some studies show that HGH accelerates bone maturation in puberty which may impede future growth.

Finally, it appears that the medical necessity standard for covering HGH is frequently narrowed or broadened on an individual basis. On the one hand, insurers are under pressure not to cover expensive procedures that could be considered more cosmetic than medical. In contrast, the medical necessity definition is sometimes expanded to include idiopathic short stature, frequently on the basis of psychological health concerns. For example, parents of children with idiopathic short stature may view normal physical development as an important component of emotional well-being, and thus request that physicians prescribe HGH. In fact, one study found that 40 percent of HGH prescriptions were written for children with idiopathic short stature. However, insurers, one step removed from such influences, approve these claims only one percent of the time.

Autologous Bone Marrow Transplant

An analysis of ABMT with high dose chemotherapy for the treatment of breast cancer illustrates the unique nature of last chance therapy and the role of litigation, legislation, and public opinion in coverage decisions. This procedure involves extracting a patient's bone marrow during high dose chemotherapy and re-infusing the marrow once the procedure is complete. The cost of this relatively risky procedure exceeds \$100,000 as compared to conventional chemotherapy, which costs between \$15,000 and \$40,000.

The National Cancer Institute reports that ABMT may be superior to standard chemotherapy for advanced breast cancer, however, researchers currently lack definitive evidence to support this finding. Widespread availability of ABMT coverage preceded clinical evidence of efficacy in part as a result of a number of high visibility lawsuits. In 1992, for example, a California jury awarded \$89 million to a man whose wife died of breast cancer after her insurer refused to pay for an ABMT. Such court rulings have encouraged insurers to prematurely include ABMT coverage in their benefit packages. In fact, ten states including Massachusetts currently mandate health insurers to provide ABMT coverage. Ironically, the availability of insurance coverage for ABMT has confounded efforts to complete large scale clinical trials to test its effectiveness because many women refuse to participate in trials for fear of being randomly assigned to a control group and thus barred from the treatment.

Without proven efficacy, a traditional cost-effectiveness analysis would likely preclude a decision to cover ABMT. One study calculated the cost-effectiveness ratio of the treatment at \$97,000 per quality-adjusted life year saved (as opposed to the average charge of the treatment), a figure more than ten times that of routine chemotherapy. However, public outrage from high profile denials of care reflect the value Americans often place on a single human life, as well as the current negative HMO climate. This tension between cost-effectiveness and public sentiment highlights the difficulties inherent in reconciling cost-effectiveness with ethical considerations.

New Developments

With increasing frequency, an independent review process is used by insurers facing difficult individual coverage decisions. Most recently, California became the first state to require plans to establish a mandatory external review for individual appeals. The Friedman-Knowles Experimental Treatment Act, effective this July, mandated independent appeal for denials of experimental therapies for conditions likely to cause death within two years. Some insurers also are voluntarily adopting external review processes. For example, Empire Blue Cross Blue Shield of New York honors all requests by terminally ill patients for independent reviews on experimental treatment denials.

Independent appeals theoretically protect patients from decisions that prioritize cost control over care. Furthermore, some HMOs are beginning to view external reviews as protection against liability. From a policy perspective, external appeals laws provide an alternative to the piecemeal legislative health mandates that have proliferated over the last few years. In effect, these appeals aim at improving the decision-making process without mandating coverage of disease specific treatments.

According to a recent survey conducted by the Kaiser Family Foundation and Harvard University, 88 percent of the public favor the right to independent public review. Given its popularity, it is not surprising that an external appeal provision has appeared in Patient Bill of Rights legislation at both the federal level and within Massachusetts. In the Commonwealth, both the House and Senate approved external appeal provisions as part of pending HMO legislation. The House bill grants the reviewer narrow authority over whether care is required under the HMO contract's definition of medical necessity. In contrast, the Senate bill requires the independent reviewer to assess the medical necessity of the treatment, rather than solely evaluating whether it is required as part of the contract. The differences between these two bills have yet to be reconciled.

Federal legislative proposals also include external review provisions. As this publication goes to print, both Republican and Democratic versions of the HMO legislation include provisions for external appeal for denials of care. However, the Republican proposal limits external review to

disputes regarding medical necessity for treatments costing more than \$1,000. If enacted, federal legislation would preempt state independent appeals provisions. This legislation could also potentially alter the ERISA law, and thereby apply to employees in self-insured plans.

Conclusion

Massachusetts insurers and employers have developed processes for evaluating whether to cover new therapies. Despite these processes, developing coverage policies remains as much an art as an exact science. These decisions impact the range of human experience from birth and child rearing to negotiating treatment for end-stage disease. In addition, human differences demand that coverage decisions be made on an individual as well as a categorical basis.

While medical necessity is the current guiding standard for defining coverage, the utility of this concept is limited by its vulnerability to interpretation. Non-clinical factors such as mandate legislation, litigation, and public opinion necessarily affect insurer decisions regarding coverage. The ultimate role these factors will play remains unclear.

By deferring to a financially disinterested party, independent reviews of appeals may be part of the answer. Over time, these reviews will likely become a more standard component of coverage decision-making. However, deciding coverage is inevitably an ethically challenging and politicized process often with significant financial repercussions. Furthermore, given the fast pace of technological innovation, these types of difficult coverage questions can only be expected to increase.

Did you know?

Foreign Patients Impact Massachusetts Hospital Revenue

Massachusetts hospitals are known and respected throughout the world for their high quality medical care. Many hospitals actively encourage foreign patients, who can be a significant source of revenue because they generally pay full charges for their medical care. In addition, average charges for foreign patients are substantially higher than for U.S. residents. While foreign patients visit Massachusetts hospitals for a wide variety of procedures, most come for the treatment of life-threatening conditions such as cancer and heart disease. The following tables highlight characteristics of foreign inpatients and the hospitals that care for them.

Characteristics of Foreign Inpatients, 1997	Foreign Patients	All Other Patients
Number of Discharges	654	769,954
Average Length of Stay	7.1 days	5.1 days
Average Charges	\$22,688	\$10,150
Average Age	48	49
Percent Male	57.6%	42.7%
Percent Female	42.4%	58.3%

Most Common Procedures for Foreign Inpatients, 1997

Craniotomy (e.g., for malignant and benign brain tumors)	38
Coronary Bypass	19
Major Joint and Limb Reattachment	14
Major Chest Procedures (e.g., for throat and lung cancer)	14
Back and Neck Procedures (e.g., for intervertebral disc disorders)	12
Skin Graft	10

Hospitals with the Most Foreign Inpatients, 1997

Massachusetts General Hospital	327
Brigham and Women's Hospital	128
Lahey Hitchcock Medical Center	68
All Others (26 hospitals)	131

Source: Massachusetts Division of Health Care Financing and Policy, Fiscal Year 1997 Hospital Case Mix and Charge Database.

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WORKING UNINSURED: A PRIORITY FOR HEALTH INSURANCE REFORM

Results from the 1998 Survey of
Health Insurance Status of Massa-
chusetts Residents indicate that, at the

time the survey was completed, adults between 18 and 64 years of age accounted for more than 80% of all non-elderly uninsured people in Massachusetts¹ (see Figure 1).

Nearly 75% of these adults, or about 300,000 people, were working uninsured and more than two-thirds of the working uninsured were younger adults 18-39 years of age. Therefore, younger working adults were the segment of the population most likely, while children 0-17 years of age were *least* likely, to be uninsured among those under 65 years of age.

Distribution of Uninsured Individuals Under Age 65, 1998

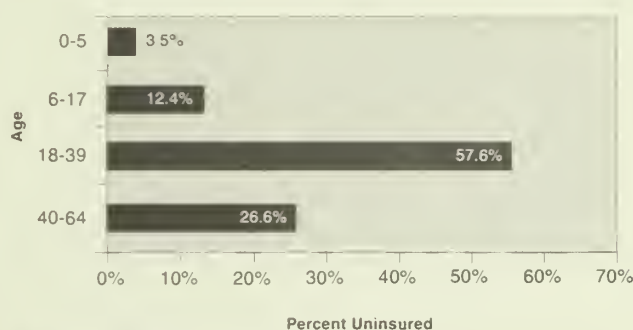


Figure 1

The 1998 study was conducted by the Center for Survey Research (CSR) at the University of Massachusetts, on behalf of the Massachusetts Division of Health Care Finance and Policy (DHCFP), pursuant to the mandate established in Section 25 of Chapter 203 of the Acts of 1996, "An Act Providing for Improved Access to Health Care." The study was conducted in two phases: from February through July 1998 the CSR conducted over 2,600 telephone surveys, and during the summer of 1998 an additional 1,076 field surveys were conducted, including 691 in-person interviews. In total, the CSR collected comprehensive, health insurance-related information on approximately 10,000 non-institutionalized Massachusetts residents.^{2,3}

The low prevalence of uninsurance among children on the one hand, and the relatively high rate of uninsurance among working adults on the other, illustrates the effectiveness of recent MassHealth expansions aimed at children and the timeliness of the current focus on expanding health insurance coverage to working uninsured individuals. This issue of *Healthpoint* uses the survey data to describe the characteristics of the working uninsured population at the time the study was conducted, and discusses policy measures currently being implemented to extend coverage to this vulnerable group.

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A Profile of the Working Uninsured Population

A majority (62.5%) of working uninsured were men, 18-39 years of age. While 43% of working uninsured were low-income residents, with household incomes below 200% of the federal poverty level (FPL), the poorest of the low-income residents—those with household incomes below 133% of FPL—constituted the largest single group among low-income working uninsured (see Figure 2).

Distribution of Working Uninsured Individuals by Income, 1998

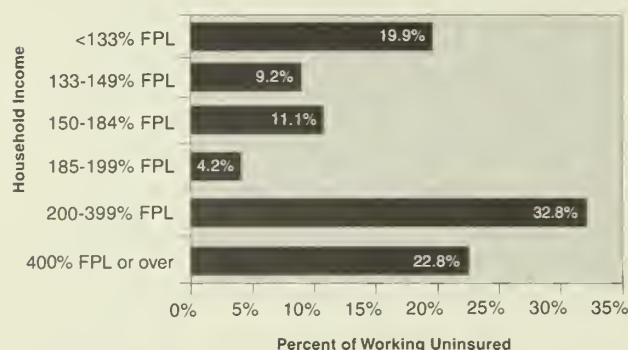


Figure 2

Employment Status. About two-thirds of working uninsured worked for one or more employer, about 21% were self-employed; and close to 12% reported being self-employed *and* working for an employer. Younger adults were more likely to be working for one or more employers and less likely to be self-employed than were adults 40 years of age or older. A majority, about 78%, of all working uninsured were employed in small firms with up to 50 employees.

Potential for Coverage through Current Employment. Over 28% of working uninsured adults, or an estimated 80,000 people statewide, reported that they were eligible for health insurance coverage through their current employer. About 40% of these people worked for small firms with up to 50 employees. A majority (67%) of the more than 40,000 people who reported that they chose not to get employer-sponsored coverage because of the cost, were adults younger than age 40. A little over 87% of all working uninsured reported that they would be willing to pay for low-cost health insurance coverage, if available. Nearly 38% of the working uninsured said they would be willing to pay \$100 to \$300 a month, while 60% expressed a willingness to pay up to \$100 a month for coverage.

Health Service Utilization, Access and Health Status. In the year prior to the survey, about 52% of working uninsured reported no emergency room utilization, and 55% reported no outpatient utilization. More than two-thirds of those who reported using health care services—in a physician's office, emergency room, or hospital inpatient setting—were younger adults. Over one-fifth of working uninsured reported not having had access to needed care, with cost cited as the most common reason.

More than half of those who reported having a chronic condition and nearly half of those who reported having a disability were younger adults. All respondents who reported having depression/anxiety, arthritis, and diabetes were older adults, while all respondents reporting paralysis, asthma/respiratory illnesses, migraine, and disabilities associated with the knee and ankle were adults younger than 40 years of age. However, a majority (66%) of the working uninsured population reported that, overall, they were in excellent to very good health during the year prior to the survey.

Policy Implications

In summary, uninsured individuals in Massachusetts are predominantly younger adults working for small firms. Despite being eligible for health care coverage through their employer, they are

often uninsured due to the cost of coverage; but willing to purchase low-cost health care coverage, if available.

Impact of Being Uninsured on Health Status. Lack of coverage and cost of care are major barriers to accessing needed health care. These barriers influence care-seeking behavior among the uninsured in that they delay accessing care, and are more likely to receive care in inappropriate settings such as hospital emergency rooms. Delayed care substantially increases the risk of higher and prolonged (chronic) illness in this population. This fact has enormous implications not only on their health status, but also on financing or subsidizing the care of uninsured adults now and, more importantly, as they grow older.

Extending Health Care Coverage to the Working Uninsured Population. Several key findings from the 1998 health insurance survey reaffirm that Massachusetts is moving forward in the appropriate direction by initiating health insurance expansions targeted toward the working uninsured population:

- incremental health reform has reduced the prevalence of uninsurance among children;
- employer-sponsored coverage remains the mainstay of health insurance in Massachusetts;
- small employers are less likely to provide affordable health insurance to their employees;
- adults working for small employers are more likely to lack access to optimal care; and
- barriers to timely and appropriate care adversely affect the health of the uninsured adult population which, while relatively healthy now, will enter middle age at a disadvantage.

Current Policy Initiative in Massachusetts. State policymakers have begun the process of extending access to health care coverage to the working uninsured. The Massachusetts Division of Medical Assistance is authorized to establish an insurance reimbursement program (IRP) under the provisions of Chapter 47 of the Acts of 1997, "An Act Assisting in Making Health Care Available to Low-Income Uninsured and Underinsured Residents of the Commonwealth." The goal of the IRP is to encourage small employers (with no more than 50 employees) to offer health insurance to their employees, or to assist them in retaining coverage. The IRP consists of an employee subsidy (premium assistance) program, and an employer incentive (insurance partnership) program.

The premium assistance program, offered through MassHealth Family Assistance, subsidizes private health insurance premiums for eligible citizens who have access to coverage through their employer. In order to receive the benefit, the employer must contribute at least 50% to the monthly cost of the insurance. Premium assistance is designed to treat the insured and uninsured workers of small businesses equitably—both will be offered assistance in covering the cost of premiums. Premium assistance is also designed to slow or halt the gradual shift away from employer-sponsored coverage by making insurance more affordable to workers and small employers.

The Insurance Partnership (formerly the IRP employer incentive program) provides payments to small employers who offer or begin to offer health insurance coverage to their employees. For a small employer to qualify, they must contribute at least 50% to the cost of coverage. Implementation of the Insurance Partnership will begin in January 1999 with the enrollment of very small groups (generally small firms with under 10 employees) and eligible adults into the programs. The program is scheduled to be made available to all eligible groups of businesses and individuals in July 1999.

Moving Forward. Massachusetts is one of very few states to have successfully expanded access to health care coverage to almost all its uninsured children, using an incremental approach to health reform. This demonstrated success provides state policymakers with a practical model and the administrative infrastructure to implement incremental reform toward expanding health care access to the working uninsured. The success of the program, however, requires that policymakers periodically assess the impact of environmental changes such as inflation in insurance premiums and prevailing labor force trends on the dynamics of health insurance, and that program beneficiaries, primarily small business employers and employees, engage in responsible and effective partnerships with program sponsors.

Endnotes

1. An estimated 500,000 children age 19 and under are insured in the state at the time the study was conducted. This number is derived by extrapolating the percent of uninsured among a household's residents (with 1 year of age or older) from the 1997 Census of the United States to the 1997 Census of the United States for Massachusetts at the time of the study. This population estimate included the 1996-1997 data on the enrollment of the persons of 19 years of age or under in the relevant public programs. We were able to obtain this data only for 1996/1997 of the study from the survey, as a result of the use of the 1996/1997 data.
2. Information provided in this section was derived from data collected from 2 out of 3 Massachusetts households surveyed during a pilot phase of the study. These households contributed the baseline survey data. The sample was drawn from the random-digit-dial method.

Further Reading

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Did you know?

Massachusetts HMO Pharmacy Spending and Utilization, 1997*

The recent DHCFP report, *HMO Rate Analysis*, includes Massachusetts HMO spending, unit cost and utilization data from 1996 and 1997. The data indicate that total HMO spending per member per month rose by 2.3% in 1997 over 1996. The increase resulted from higher medical spending, entirely attributable to increases in pharmacy spending and professional fees. While still representing a relatively small share of total medical spending, 10.3% on average, pharmacy expenses increased more than any other major service category in 1997. Recent media attention to the increasing cost of pharmacy benefits is supported by the findings in *HMO Rate Analysis* which identified an average 6.4% increase in pharmacy spending for Massachusetts HMOs' fully-insured commercial membership in 1997 over 1996. The wide variation in pharmacy spending, cost per prescription and utilization in 1997 is highlighted below.

	Low	Median	High
Pharmacy Spending Per Member Per Month (Excluding Copayments)	\$14.66	\$17.25	\$33.40
Average Cost per Prescription (Excluding Copayments)	\$22.80	\$26.34	\$32.23
Brand Name	\$35.88	\$44.26	\$51.62
Generic	\$6.02	\$7.06	\$12.11
Average Prescriptions Per Member Per Year	6.7	8.3	12.4
Brand Name	3.6	4.3	7.0
Generic	3.0	3.9	5.4

* Data from the 1997 HMO Rate Analysis report, published by the DHCFP in 1998.

Source: Commonwealth of Massachusetts, Department of Health and Human Services, Division of Health Care Financing, 1998. The data were derived from the 1997 HMO Rate Analysis report, published by the DHCFP in 1998.

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WHAT'S DRIVING

PRESCRIPTION DRUG COSTS?

Prescription drugs and their associated costs are currently receiving a lot of attention from health care organizations, policy makers and consumers. While inflation, including medical inflation, has been at its lowest in twenty years, prescription drugs have been primarily responsible for recent increases (sometimes steep) in insurance premiums and patient out of pocket expenses. According to IMS Health, Inc., a national company that tracks prescription data, prescription sales are expected to produce a compounded average growth rate of 9.8% over the 1998-2002 period. This edition of *Healthpoint* examines *why* prescription drugs are responsible for a larger share of the health care budget and discusses the impact of drug utilization on the provision of cost-effective, quality health care in Massachusetts.

The Fastest Growing Component of Health Care Costs

The prescription drug category is currently the fastest growing component of the health care budget. While until recently prescription drugs represented only a small fraction of the health care budget, today they represent up to 15% of total health expenditures for certain insurers, with some reporting prescription drug budgets that exceed the annual amount spent on doctors.¹ Drug costs, if unchecked, could exceed hospital costs (typically the most expensive component of health care) in a few years. The rapid increase in spending for prescription drugs is one reason employers expect premiums to rise anywhere from 4% to 15% in 1999, after years of no or low single-digit increases.² In Massachusetts, the Medicaid program has seen drug spending rise from 9% of its total expenditures in 1995 to a projected 15% in 1999.

A number of reasons are cited for the increased spending on prescription drugs. Among these are: 1) recent advances in research resulting in new and more expensive drugs to treat a multitude of diseases; 2) an aging population that will double to over 70 million people over age 65 by the year 2030; and 3) increasing consumer demand for prescriptions, driven by their health needs, direct consumer advertising, and in some cases, increased third party coverage.³

More New Drugs

For the most part, drugs currently on the market have played a limited role in the growth of prescription drug expenses. Rather, that growth is based on expensive new

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Number 13 April 1999

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brand name drugs that have recently entered the market and the demand that they create. In addition, the volume of prescriptions dispensed by pharmacies has been increasing an average of 5% per year over the past several years, reaching 2.4 billion prescriptions dispensed in 1997.⁴ In Massachusetts, data provided by 11 Massachusetts HMOs, indicate that the overall number of prescriptions filled in 1997 compared to 1996 increased 6.8% for their fully insured commercial population.

When brand name drugs enter the market, they enjoy a period of patent protection for up to 20 years that is intended to assist drug manufacturers in recouping their research and development costs. The price of a drug is determined by a number of factors: the perceived value of the drug in terms of improving quality of life or health outcomes, whether the drug is a substitute for either a comparable drug or a surgical procedure, and its research and development costs. Historically, most new drugs entered the market at less than \$2 a pill, but now a number of new products go for much more. Rezulin, a treatment for diabetes is about \$4 a pill while Viagra, the impotence drug is \$7-10 dollars a pill. The new cox-2 inhibitors for arthritis treatment will replace drugs costing about 20 cents with ones averaging \$2.50. New biotechnology products, such as erythropoietin for the treatment of anemia in patients with kidney disease, may cost up to \$7,000 dollars or more a year.

Brand Name versus Generic Drugs

Brand name drugs comprise about 50% of all prescriptions filled, but they account for 80% of pharmaceutical spending.⁵ Because most new drugs have no generic equivalent, there is no substitute for their use. In Massachusetts, state law requires pharmacists to substitute a generic drug (if available) for a brand name drug unless a physician writes "no substitution". The state is considered to have a high generic substitution rate—the majority of prescriptions are filled with a generic equivalent, if available. Nevertheless, data from the fully insured commercial members of the eleven Massachusetts HMOs referenced above show that in 1997 there were 15% more brand name prescriptions filled than generics. With a presumably well managed drug benefit in place, this is most likely due to the lack of generic equivalents.

International Drug Pricing

United States firms lead the world in drug development, producing almost half of the new drugs introduced around the world between 1974 and 1994. Drug makers cite the high cost of putting a drug through clinical trials (up to \$150 million dollars or more a drug), with only a small fraction ever making it to market as one of the key reasons that brand name drugs are considerably more expensive than generics. However, brand name drugs typically see gross profits of over 90%, with net profits for the industry at about 18%.⁶ Furthermore, prices for the same drug products in other countries such as Canada are typically 40% less than in the U.S. Most other countries, including Canada, have price controls limiting how much will be paid for drug products. Deep opposition by the pharmaceutical industry to this approach has made this politically infeasible in the U.S.

Advertising Appeal

New direct-to-consumer advertising campaigns that influence consumer demand for new drug products is seen as at least partially responsible for the recent dramatic increase in drug expenditures, especially among brand name drugs. In 1997, the FDA lifted restrictions on how manufacturers can advertise prescription drugs. In 1998, drug manufacturers spent over \$1.3 billion in direct-to-consumer advertising, a 50% increase from 1997.⁷ One of the most widely prescribed medications,

Claritan, a non-sedating antihistamine, is also one of the most heavily advertised products to consumers. Overall, according to IMS health, pharmaceutical manufacturers will spend about \$11 billion this year on marketing compared to approximately \$24 billion on research and development.^{8,9}

Third Party Reimbursement

While it means more individuals have access to life saving therapies, insurance coverage is seen as a big contributor to the increased use of prescription drug therapies. Managed care has been quick to adopt drug therapy as an approach to prevent hospitalization and reduce long term costs of care, raising the question of whether insurers have at least partially offset the increased cost of drugs by savings in hospitalizations. And while third party payers have taken a larger role in managing and controlling reimbursement for prescription drugs, many Americans are either not insured at all, have a hospitalization policy with no drug coverage, or are covered under Medicare which does not include drug coverage. Rapidly increasing costs to insurers contribute to demands for increased cost sharing by patients and consideration of capping benefits. Recently, some Massachusetts managed care plans announced the implementation of increased (sometimes substantial) co-payments on certain brand name drugs if an alternative is available in the formulary. Even with insurance coverage, prescription drugs are the highest out of pocket expense category for individuals due to co-payment requirements.

Drug Problems for the Elderly

While the elderly make up only 12% of U.S. population, they use almost 35% of the prescription drugs dispensed. When Medicare was enacted in 1965, prescription drugs were a minor part of the treatment for most conditions, but today the primary treatment for these same conditions is likely to rely heavily on drug therapies. A recent Congressional commission to reform Medicare failed to reach consensus on a proposal to revamp the existing program with the sticking point being how (*not* whether) Medicare should provide prescription drug coverage. One concern is the very mixed support among seniors for raising premiums to pay for drug coverage since 65% of seniors already have drug coverage (see Figure 1). In 1988, when Congress passed a law to provide long-term care and prescription drug benefits through the Medicare program, many elderly reacted angrily to the increase in their Medicare premiums forcing Congress to repeal the law. Today, although drugs may reduce some costs of care, the addition of a drug benefit is projected to add at least \$20 billion dollars to the existing Medicare program per year.

In 1998, Sixty-Five Percent of Medicare Beneficiaries Had Prescription Drug Coverage

The Search for Solutions

Policy makers face an array of issues in the debate over prescription drug coverage. It is anticipated that new drug development will continue to increase the demand for drug therapies and consume ever-larger portions of the health care budget. Issues of parity will also arise, as individuals, whose only

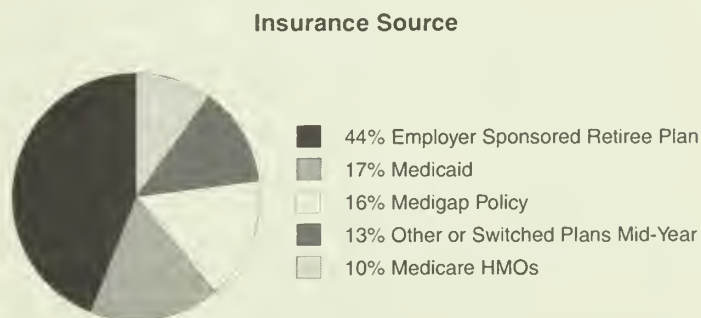


Figure 1

Source: Congressional Budget Office, "Medicare Prescription Drug Coverage," 1998.

source of treatment for a condition may be a drug therapy, may demand that they receive coverage comparable to those who undergo fully covered surgical or medical procedures for their conditions.

While waiting for a national solution to the problem, states have been hampered in their own efforts to solve the crisis by the federal preemption issue. In Massachusetts, federal preemption of Medicare laws allowed Medicare HMOs to restrict the level of coverage of prescription drugs for seniors wishing to purchase a Medicare HMO policy. While existing state pharmacy assistance programs target the most vulnerable, low-income individuals, even better off individuals are being strained by the cost to purchase needed medications. Currently, discussions in Massachusetts have focused on ensuring that all individuals have some coverage to protect against catastrophic prescription costs, expanding the existing Senior Pharmacy program or establishing a statewide purchasing program with rebates.

Another area of contention is the pricing of drugs. Without a national program such as Medicare purchasing drugs, individuals pay high retail prices for drugs due to cost shifting from discounts that third party payers negotiate. One reason there is strong pharmaceutical company opposition to the broadening of Medicare to include drug coverage is the fear that if the federal program covers drugs, they will negotiate discounts or price ceilings.

The issue over prescription drug coverage is similar to the broader issues surrounding access to health insurance coverage in general. While a majority is comfortable with their insurance and drug benefits coverage, the uninsured and underinsured minority is seeking ways to afford health insurance and benefits increasingly out of their reach.

Endnotes

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5. Ibid.
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Did you know?

Observation Stays Are a Significant Portion of Hospital Care

The Division of Health Care Finance and Policy has collected observation data from approximately 83 acute hospitals since the quarter beginning July 1, 1997. The first full year for reporting observation data is 1998. While the types of observation services provided may differ by hospital and payer, observation services may generally be defined as "services furnished on a hospital's premises which are necessary to evaluate a patient's condition, determine the need for possible admission to the hospital, and provide treatment. These services include the use of a bed and periodic monitoring by a hospital's physician, nursing and other staff."

	1998 Observation Stays	1998 Inpatient Stays
Total Number	150,000	775,054
Total Charges	\$500 Million	\$8.3 Billion
Median Charge	\$2,400	\$5,982
Average Length of Stay	21 hours	5.1 days
Top Payer	HMOs	Medicare
Top Three Conditions	cardiac maternity related respiratory	maternity cardiac respiratory

Source: Massachusetts Division of Health Care Finance and Policy, using 1998 Hospital Care, Median Charge Data, and 1998 Observation Data.

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MARKET CHANGE AFFECTS COMMUNITY HEALTH CENTERS

University of Massachusetts
Community Health Centers (CHCs) provide
a crucial link to health services for lower
income individuals throughout Massachu-

setts. Despite tremendous change in the Commonwealth's health care market recently, the mission of these organizations remains largely the same since their founding three decades ago. A key component of the state's safety net, CHCs provide accessible, high quality primary care services to low income residents regardless of ability to pay.

CHCs always depended on hospitals, usually municipal safety net hospitals, to provide an inpatient site for their sick patients. This relationship reflected a relative lack of interest by private non-profit hospitals in CHCs' often uninsured patients. However, seismic changes in the Massachusetts health care industry in the early 1990s created new negotiating opportunities for Boston CHCs. This issue of *Healthpoint* examines this evolution with specific attention to whether more involvement with CHCs by private non-profit hospitals has served the hospitals, the CHCs, and above all the patients. To prepare this analysis, the Division of Health Care Finance and Policy conducted extensive interviews with a variety of interested parties, including hospital administrators, CHC directors, and patient advocates.

A continuum of different partnership arrangements is possible between CHCs and hospitals. Under the tightest arrangement, a hospital may directly license a CHC, budgeting and administering it as any other hospital department. Alternatively, a variety of affiliation agreements are negotiated with greater or lesser exclusivity and interdependence. One noticeable trend examined here is more formal arrangements between CHCs and hospitals spurred at least in part by the promise of substantial capital investment in certain CHCs by hospitals.

Hospitals Seek Stronger Ties

A number of factors explain the dramatic change in the worth of CHCs to hospitals. The most important impetus, market consolidation, started in the acute sector but eventually rippled through the industry. The announcement of the creation of Partners

Massachusetts Community Health Centers 46 Centers at 99 Sites

Location	Ownership
28 in Boston	30 free-standing
18 in the rest of the state	16 hospital licensed

628,000 patients served
3 million patient visits
\$312.5 million in total revenue*

*Note: see Figure 1 on page 2 for a breakdown of revenue sources
Source: Massachusetts League of Community Health Centers, 1998

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Number 14 July 1999

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HealthCare System in December 1993 was the catalyst that eventually resulted in reactive alliances throughout the state. Partners, and subsequently other systems, pursued a strategy of consolidating market power in an effort to create efficiency, reduce costs, and ensure patient stream. Only by taking these steps could the systems strengthen their own negotiating capacity with the increasingly dominant managed care organizations. Lining up "covered lives" by linking with CHCs and physician practices was an important strategy for surviving under managed care capitation agreements. CHCs gained negotiating pull as hospital systems scrambled to broaden and integrate their own networks. Compared to the purchase of physician practices (which the private non-profit hospitals also did), CHC affiliations provided hospitals the opportunity to expand their primary care practice and garner referrals while assuming significantly less risk and tapping into a different market base.

Second, several CHC administrators cite a report commissioned by the Boston Department of Health and Hospitals as setting the stage for hospitals to increase involvement in community health even before market forces compelled that strategy. This 1993 report, by Professor Nancy Kane of the Harvard School of Public Health, charged that private non-profit hospitals were understating profits and that the weakest hospitals financially made the strongest commitment to Boston's poor. Moral pressure generated by the Kane report added fuel to a growing interest in community benefits. During this period, a few non-profit hospitals in other states lost tax exempt status over this issue and six states including California enacted community benefit mandates. These developments led to the introduction of legislation in Massachusetts calling for hospitals to provide funding to health centers and, ultimately, to the creation of voluntary community benefit guidelines. For many hospitals, relationships with CHCs serve as a cornerstone for fulfilling these obligations.

A number of interviewees also believe that MassHealth expansions and full funding of the Uncompensated Care Pool have strengthened the negotiating clout of CHCs. The former extends insurance coverage to otherwise uninsured residents and the latter reimburses providers nearly at cost for their uninsured patients. Since July 1997, more than 200,000 individuals have enrolled in MassHealth as a result of state reform efforts, increasing total enrollment by 37% as of March 1999.¹ In this era of sustained pressure to reduce both admissions and lengths of stay, hospitals view these patients as a viable means of maintaining occupied beds. Moreover, expansion of the Uncompensated Care Pool in 1992 allowed CHCs to access free care reimbursement quelling hospital anxiety regarding the fiscal solvency of potential CHC affiliates.

**Massachusetts Community Health Centers
FY98 Sources of Revenue**

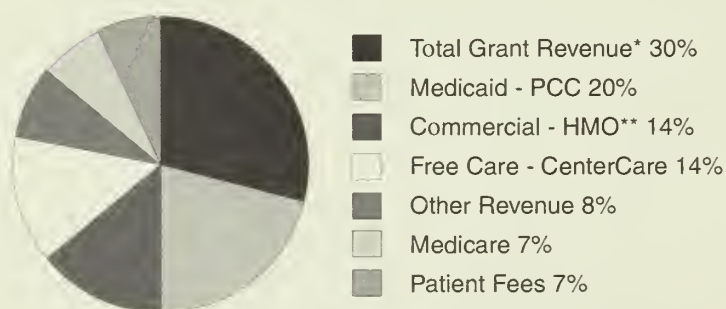


Figure 1

Cinderella Centers

From the CHC perspective, fiscal considerations figured prominently in their interest in pursuing stronger hospital partnerships. CHCs regularly operate with minimal cash reserves and lack resources to undertake capital improvements. They viewed the perceived deep pockets of hospitals as a means of financing new facilities and capital intensive information

systems. Through spirited bidding among interested hospital suitors for affiliation contracts, Boston CHCs negotiated for needed project underwriting. In fact, one concrete result of market consolidation is the rebuilding of many Boston area health centers financed significantly by hospitals. This flurry of hospital investment activity prompted a *Boston Globe* reporter to characterize Boston CHCs as "Cinderella centers" in late 1995.² Despite these substantial investments, however, CHCs report no pressure to dilute the composition of their community-based boards of directors with hospital personnel.

Health center administrators outside the Boston area portrayed a starkly different experience with their area hospitals. The courting frenzy that benefited the Boston area CHCs simply did not occur elsewhere. The difference appears to lie in the much lower level of hospital competition outside Boston. A health center located in a market dominated by a single hospital system continues to exercise little bargaining power in the absence of choice for affiliation. Conversely, no incentive exists for a dominant hospital to court a health center. While no CHC administrators outside Boston claim to be *worse off* in the aftermath of market consolidation, they never received the offers of capital infusion enjoyed by Boston-based CHCs.

Have Patients Benefited?

Boston health centers identify numerous improvements in patient care resulting from tighter affiliations with hospitals. Specifically, affiliations facilitate improved coordination and communication with hospital-based specialists, in part through the upgrading and integrating of CHC information systems. Computer linkages now support shared medical records and facilitate jointly run public health initiatives. For example, one Boston health center and its hospital partner collaborate on a breast cancer screening data collection initiative. Through this effort, they hope to establish a baseline of current utilization and to evaluate barriers to access.

Such collaborations represent the potential benefits hospital affiliation can bring to CHC clinical capacity. Increasing on-site specialty care, expanding women's health services, and rotating medical school students and residents through the health centers all benefit patient care. Early concern that affiliation contracts could lead to the curtailing of referral choice has not materialized. CHC administrators also note the advantage of access to the tremendous purchasing power of hospitals. Finally, hospital administrators recognize that CHCs teach them valuable lessons about providing culturally appropriate care to diverse populations which also ultimately improves patient care.

On the other hand, CHC administrators say that the same systemic change that brought increased market power to them has made navigating through the system more difficult for their patients, as it has for all managed care patients. Managed care requirements such as obtaining permission for specialist or emergency care are particularly difficult for individuals with language difficulties or limited education.

Policy Implications

Transformation of the hospital industry played the predominant role in advancing CHC negotiating power in the Boston marketplace. The impetus behind market consolidation traces back to deregulation of the hospital industry by the state legislature and the double-digit health care spending growth of the early 1990s. These dynamics resulted in the explosive growth of managed care plans, thereby greatly increasing insurer negotiating power. In reaction, two of the largest hospitals in the state formed an historic partnership to gain a stronger hand with managed care. This alliance,

at the time described as a "stunning" development³ by the *Boston Globe*, set the stage for competitors to reactively follow suit and feverishly seek out primary care alliances. In turn, this led to the strengthening of CHC negotiating power in the Boston area.

The underlying policy of state government throughout these events was a hand off to market forces. This policy benefited CHCs able to harness market forces to increase financial stability and augment clinical resources without significantly compromising their historic mission. However, its result elsewhere in the state is less sanguine. Generally, the local dominance of single hospital systems eliminated the need to bid for CHC favor. This dynamic bears monitoring to ensure that non-metropolitan CHCs do not falter as resources become increasingly strained.

Another policy question is to what degree do community benefit guidelines affect CHCs. After only a few years, formal evaluation of this voluntary program may be premature. However, preliminary anecdotal evidence suggests that, at minimum, guidelines raise the profile and the bar for community involvement by hospitals. In the words of one administrator, voluntary guidelines "add community benefits to the checklist of issues hospitals need to be concerned about."

However, the strength of voluntary guidelines and the depth of hospitals' philosophical commitment to CHCs will be tested in an era of constrained resources. As cuts from the Balanced Budget Act of 1997 and slimmer margins take their toll, will Boston CHCs continue to enjoy their favored status with hospitals? Will competition for primary care patients increasingly pit a CHC against its affiliated hospital's primary care medical staff or its purchased medical practice? As the health care market continues to evolve rapidly, policymakers should monitor CHCs to ensure that they can continue to meet the particular health needs of their often vulnerable communities.

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Did you know?

Hospital Margins Decreased Between 1997 and 1998

The ratio of total profit to total expense (total margin) for the Massachusetts acute care hospital industry showed an overall decrease from 1997 to 1998 and more hospitals had negative total margins in 1998. The most profitable hospitals in 1997 were the same as those in 1998, and performed even better. The least profitable hospitals in 1997 were different than those in 1998 and showed even lower margins. A soon to be released DHCFP report will evaluate the overall financial health of the hospital industry.



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THE LINK BETWEEN EMPLOYMENT AND HEALTH INSURANCE

Most adult Americans under age 65 who have privately purchased health insurance obtain it through their employer or their spouse's employer. Linking health insurance to work began in the 1940s, when firms began to offer insurance in response to a labor shortage and the imposition of a wage freeze by the National War Labor Board during World War II. By 1987, the number of non-elderly Americans covered by employer sponsored plans peaked at 69.2% but declined to 64.2% nationally by 1997¹ and is expected to continue to drop. In 1998, nearly 66% of the insured non-elderly residents of Massachusetts obtained their coverage through work.² Americans have become so accustomed to linking health insurance with work that they rarely consider the consequences of relying on employers to purchase their coverage. As the workplace, family, and world economy change, and health care costs continue to rise, however, it is time to examine this uniquely American system of coupling employment and health insurance. This issue of *Healthpoint* looks at the benefits of this system, why fewer people are served by it, and offers policy questions to consider.

Employer Sponsored Health Care Does Many Things Well

Although 41% of adults with employer-based coverage have no choice of health plans,³ private insurance purchased by employers is almost always less expensive and more comprehensive than private coverage purchased individually. The lower premium price is due to three factors. First, insuring groups spreads the administrative cost of purchasing insurance among many individuals. Second, large organizations obtain better prices. Finally, neither employers nor workers pay taxes on the employer paid portion of insurance premiums and often workers pay their own share with pre-tax dollars.

From the insurer perspective, employees are "natural groups" to insure, coming together for reasons generally unrelated to their need for health services. Both healthy and sick individuals end up in the same risk pool, minimizing adverse selection, thereby facilitating one, more affordable rate.

The job-based system has been effective at bringing relatively healthy individuals into the market and motivating them to obtain coverage by simple payroll deduction. Purchasing health insurance through work has become a common, expected part of the employee-employer relationship. If individuals were left to purchase their own health insurance, no doubt fewer would do so.

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Number 15 October 1999

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The World Has Changed

Some of the many factors which inexorably led to the declining number of employees obtaining insurance through work include a decrease in union membership (which traditionally lobbies heavily for health insurance benefits), the globalization of the world economy (which pits American made goods against those of other countries whose health care costs are lower), and a shift from manufacturing to service industries (which are less likely to offer health insurance benefits, historically). In addition, passage of the Employment Retirement Income Security Act (ERISA) in 1974 had the unintended but widespread effect of encouraging employers to pay directly the health care claims of their own employees and eligible dependents, rather than to purchase insurance. The self-insurance strategy has become more attractive with the rising number of state mandated benefits and regulations from which self-insured companies are exempt due to federal pre-emption.

By far the largest factor affecting coverage appears to be the rapid increase in health care costs and associated premiums which have made coverage unaffordable for many. This is not surprising given that the cost of health insurance premiums increased three times faster than wages and salaries from 1987 to 1993.⁴

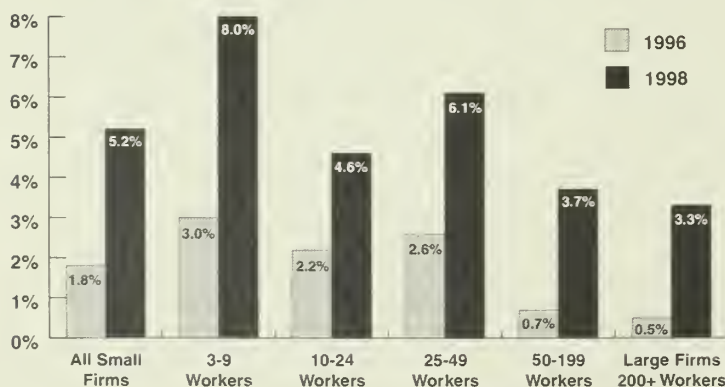
As the worker share of premiums, copayments and deductibles rises, workers increasingly turn down coverage when offered. In 1998, 17.2% of uninsured working adults in Massachusetts reported that although they were eligible to purchase health insurance through work, they turned it down due to its cost.⁵ Most economists believe the employee ultimately pays the entire insurance premium out of his overall compensation regardless of the ratio of premium cost sharing stipulated by a particular employer, as employers have a certain amount of money to spend on employee compensation regardless of how it is parceled into wages, health insurance premiums, vacation pay, pension contributions, etc. While most employees (and unions) resist higher contributions, they should be just as concerned about the rise in the total premium since that consumes compensation dollars. Of course if an employee turns down insurance from an employer who contributes even a small portion of the premium, he rarely receives that foregone compensation in cash.

Shortcomings of an Employer-Based System

Even among covered adults, a significant disadvantage to an employer-based insurance system is that the benefits are not portable from job to job. Some workers experience "job lock"—they are

essentially unable to change jobs due to a long insurance waiting period, an exclusion for a pre-existing condition or some other significant disadvantage they would experience in switching to a new employer's health plan. Workers who quit or lose their job can maintain their coverage under the Consolidated Omnibus Budget Reduction Act of 1985 (COBRA), but only for eighteen months and almost al-

Percentage Increase in Premiums Nationally by Firm Size
1996 and 1998



ways at a much higher cost. Although the federal government has improved portability under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the law applies only in certain circumstances.

Three-quarters of the country's recent job growth occurred in small businesses.⁶ Therefore, it is a significant disadvantage that small organizations tend to be charged more per person and experience steeper premium increases for health insurance than large organizations.⁷ Even while the economy flourished in Massachusetts between 1996 and 1998, the largest segment of individuals without insurance was employed by firms with less than 50 employees.⁸

Who's Not Covered by the Current System?

The American employment-based health insurance system has done many things well but only for those under its umbrella. It never served well or at all the unemployed; the part time, seasonal, off-the-books or undocumented worker; the self-employed; or the significant other or gay partner of an employee. Recently, the proportion of the population covered as dependents (a traditionally covered group) declined between 1988 and 1995 from 32.3% to 27.8%.⁹ All of these groups, including the growing number of workers who have declined employer-based insurance due to rising premiums, have contributed to the swelling number of uninsured in this country. Massachusetts has had partial success in counteracting this trend through MassHealth expansion and other programs.

Policy Considerations

Usually, firms contribute the same amount of money to the health insurance premium of each employee regardless of individual income or tax bracket. Therefore, the after-tax value of the benefit greatly favors the highest wage earners. In Massachusetts, each dollar of health insurance premium is worth \$1.72 to an employee in the highest federal and state tax brackets, but only \$1.27 to those in the lowest. Were these premiums and related expenses to be treated like cash wages, government would gain an estimated \$124.8 billion¹⁰ annually in revenue which theoretically could subsidize premiums for the low-income uninsured. Those who benefit most from the current tax exemption policy on their employer sponsored plans can best afford coverage and probably wouldn't drop it even in the face of a tax on premium contributions. On the other hand, for individuals currently buying non-group coverage on their own, premiums are generally not deductible.

Some shortcomings of employer sponsored coverage already have been addressed by the passage of COBRA and HIPAA, and in Massachusetts, by small-group market reform which somewhat improved access and affordability of coverage for workers in small businesses. As premiums continue to rise, however, we can expect employers to further reduce their contribution or cease to offer coverage. We can also expect more low wage workers to turn down coverage when offered. There are several bills in Congress to facilitate the purchase of insurance by establishing tax credits for, or increasing the deductibility of, health care and premium expenses. In 1999, the Massachusetts Division of Medical Assistance implemented the Insurance Partnership, which provides subsidies to both eligible employers and workers for the purchase of health insurance in an attempt to increase enrollment and discourage employer reliance on Medicaid as an employee safety net.

Some advocate replacing the job-based system with either an individual mandate system or a single payer system. Under the former, individuals would be required to purchase coverage, with a mechanism in place assisting them to do so affordably. However, it is feared that this could lead to a segmentation of the insurance market into healthy and high-need groups leaving few choices for

the latter. In fact, any strong support (through tax credits or subsidies) of individual purchase would attract healthy individuals for the most part. Under the single payer system, government would be the sole purchaser of health care, ensuring access to all, but opponents doubt that government can provide quality health care at affordable prices. Proposals to build a different health care system have received little political support to date for a variety of reasons, but as traditionally covered groups find their cost increasing and choice decreasing, they may add their voice to groups who have long been disadvantaged by the employment-based system.

Endnotes

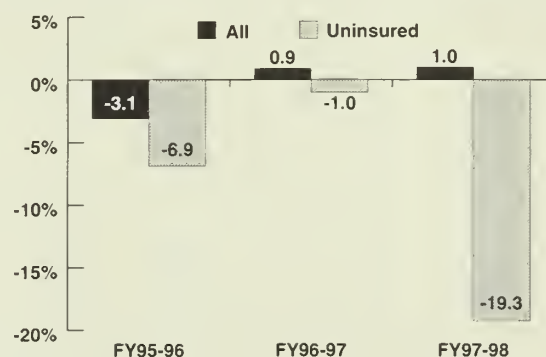
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Did you know?

Fewer Uninsured Patients Discharged from Acute Hospitals

Massachusetts uninsured* patient discharges decreased as a percent of all acute care hospital discharges from 6% in FY95 to less than 5% in FY98. The absolute number of discharges for uninsured patients dropped 26% but just 2% for all patients from FY95 to FY98. The dramatic drop from FY97 to FY98 coincides with major MassHealth expansions begun in July 1997. Median and mean charges continue to be lower for uninsured patients who are on average much younger than hospitalized patients overall. Charges for uninsured patients as a percent of all charges decreased from 5% in FY95 to 4% in FY98.

Percent Change in Number of Hospital Discharges



*Uninsured patients are those who are not enrolled in any health insurance plan. This includes those who are not enrolled in any health insurance plan.

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ORGAN DONATION AND ALLOCATION

The altruistic act of organ donation has contributed to improved health and years of life for tens of thousands of transplant recipients since the first kidney was successfully transplanted at Peter Bent Brigham Hospital in 1954. Transplantation has become an increasingly frequent procedure with 492 major organ transplants performed at ten Massachusetts hospitals in 1998,¹ accounting for about \$59 million in total hospital charges.² However, from 1988 to 1998 the number of patients on organ transplant waiting lists nationally increased by 302% (see figure on page 2). At the same time, donated organs increased by only 71% while the number of people who died each year waiting for organs increased by 225%.³

The growing disparity between organ supply and demand has intensified the debate over both the optimal means of promoting organ donation and the allocation system. A number of interested parties have a considerable stake in the ongoing debate. Among them are patients waiting for organs, hospitals and physicians defending existing programs or attempting to begin new ones, the United Network of Organ Sharing (UNOS) and the US Department of Health and Human Services each seeking greater administrative control, and states seeking to protect their citizens' and hospitals' interests. This issue of *Healthpoint* examines a number of current issues in organ donation and allocation, both nationally and in Massachusetts, and discusses a number of policy proposals designed to increase donation.

Background

The National Organ Transplant Act (NOTA) was passed by Congress in 1984 to address the need for a more equitable and efficient system for the procurement and distribution of organs. The Act called for the formation of the Organ Procurement and Transplantation Network (OPTN), a collaborative effort of organ transplant hospitals and local organ procurement organizations (OPOs), to match donors to appropriate recipients. Since 1986, administration of the OPTN has been contracted to UNOS, a private non-profit organization. The nation is divided into 11 OPTN-established geographic regions within which there are 60 OPOs that administer the program to populations ranging in size from less than one million to 12 million. Every transplant hospital is affiliated with an OPO and maintains its own transplant patient waiting list. The New England Organ Bank (NEOB) is the OPO administrator for most New England hospitals.

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Number 16 January 2000

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Currently, when an organ becomes available, the local OPO searches for an appropriate recipient within its area based on clinical criteria such as size match and blood type. Clinical matching is attempted among the sickest (Level 1) patients first, then less sick patients in that OPO area, rather than Level 1 patients in another area. If no suitable match is found within the area, recipient matching is attempted within the OPTN region, then nationally. Challenging the federal allocation rules, six states (Arizona, Louisiana, Wisconsin, South Carolina, Oklahoma, and Texas) have passed legislation requiring organs donated in their state be offered first to patients listed with transplant centers in their state.

Recent federal legislation amends the current rules governing organ allocation, including the establishment of Organ Allocation Areas to cover at least nine million residents and greater standardization of hospital eligibility protocols. The intent is to create more equitable waiting times among patients. For example, from January 1994 to December 1996 the median waiting time for a blood type O liver patient in the New England region was 958 days, versus 123 days for the same type of patient in the southern states region.⁴ In addition, OPTN regions that have a longer median waiting time for liver transplants tend to have a lower percentage of patients who receive a liver and a higher percentage who die while waiting for a liver.^{4,5} By increasing the size of allocation areas, an available organ will be checked for compatibility with a larger pool of potential recipients and, consequently, a larger pool of the sickest patients, thereby making organs more available to those most urgently in need, and presumably reducing regional variation.

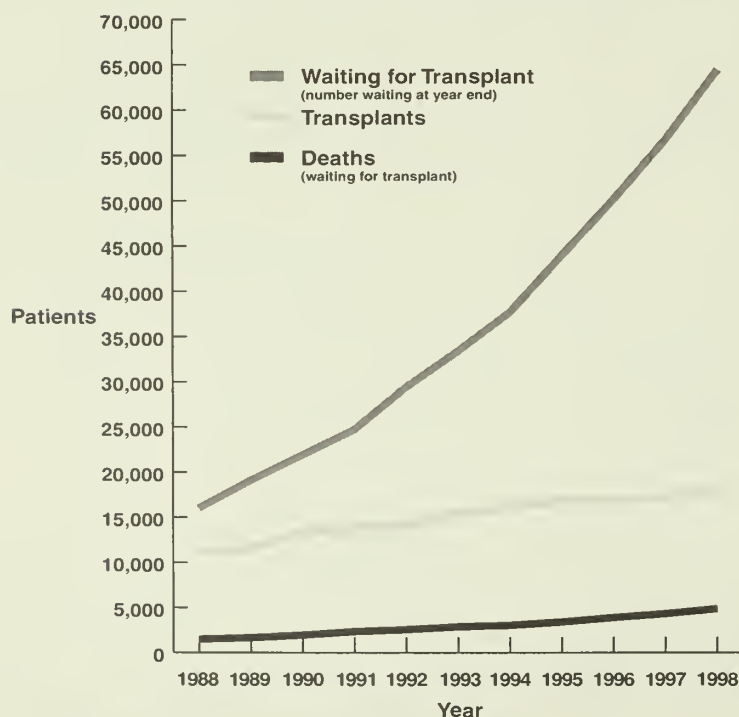
Opponents, most notably UNOS, counter that because the new rules will make organs available more frequently to the sickest patients (who tend to have worse outcomes), optimal utilization of organs will not be realized. Small and medium-sized centers tend to be in small OPO areas which facilitates access to organs for patients (from the most to the least sick) on their lists. These centers contend that the new rules will mean fewer organs for their patients, potentially

decreasing their volume below the 12 liver transplant annual minimum needed to comply with the requirement for participation in Medicare.

Massachusetts

Whereas a kidney donation is made from either a living (typically a family member) or cadaveric donor, liver, pancreas, heart and lung donors are primarily cadaveric, who most often die from intracerebral hemorrhage or accidental death (typically a motor vehicle accident). A look at the number of cadaveric donors in Massachusetts over time is a useful assessment of the relative success of donation initiatives in the state.

Major Organ Transplants: US Trend



There are approximately 2,000 "candidate" deaths in Massachusetts per year,⁶ defined as people under the age of 65 who die from intracerebral hemorrhage or accidental head injury (primarily sustained in motor vehicle accidents). From 1988 to 1997, the number of cadaveric donors at Massachusetts hospitals increased by 29%, from 83 in 1988 to 107 in 1997, relatively low compared to the 42% national increase in cadaveric donors during that period.³ A useful indicator for the state trend in donation rates over time is the number of cadaveric donors per 1000 "candidate" deaths. By this definition, donation rates increased from 42.7 donors/1000 deaths (1991-1992), to 49.3 donors/1000 deaths (1996-1997). Although not all organs donated in Massachusetts are transplanted in Massachusetts hospitals, increased local donation undoubtedly would lead to the greater availability of organs for Massachusetts residents and its transplant hospitals.

Legislation

In 1983, Massachusetts established the Organ Transplant Fund (OTF) to assist residents with uncovered costs associated with organ transplant, typically immunosuppressive drugs. Transplant surgery itself is generally covered by insurance or, for the uninsured, the Uncompensated Care Pool. The OTF is administered by the Department of Public Health (DPH) and funded by private donations, most often via a voluntary indicator on the state income tax form. The OTF, the only voluntary state assistance program in the nation, has assisted 600 Massachusetts residents with over \$2,000,000 in transplant related expenses in the last 13 years.

In 1998, HCFA amended the Medicare conditions of participation to require "routine referral" of all in-hospital deaths to the local OPO in a "timely" manner. Consequently, the specially trained NEOB staff, in collaboration with on-site medical staff, is able to make an assessment of organ donation potential and request consent from the family for donation. This situation typically results in higher rates of familial consent than if these tasks are left solely to the hospital staff.

Public Outreach

The primary, but vastly under-realized, channel for publicizing organ donation and signing up intended donors is the Massachusetts Registry of Motor Vehicles (RMV), whose license application and renewal forms ask applicants to indicate interest in the organ donor (OD) designation. However, RMV does not systematically provide information about organ donation by mail, on its website, or in its offices, nor does it routinely track the number of OD designated drivers. In contrast, Pennsylvania mandated comprehensive outreach in 1994, including the mailing of a "Greatest Gift" brochure with all registration renewal notifications, as well as deeming the OD designation on a driver's license sufficient to indicate legal consent. In Massachusetts, the OD designation is not considered legally binding; next-of-kin consent must be given for donation to occur. Although the quantitative effects of the Pennsylvania measures are difficult to determine ("routine referral" of all in-hospital deaths was mandated at the same time), the OPOs serving Pennsylvania report a 43% increase in organ donation from 1995 to 1998.⁷

Policy Implications

Ironically, improvements in transplantation medicine expanding the criteria for patient eligibility have led to an increase in the annual number of organ wait list deaths because the supply of organs cannot meet the demand. Alternative sources of organs, such as xenotransplantation (animal organs altered with human genes) or the genetically engineered "growing" of organs, are years

from practical use and carry with them uncertain public health risks. However, a number of state initiatives could increase the potential for donation in Massachusetts.

DPH is already undertaking an initiative with NEOB and trauma-center hospitals to standardize donation protocols by adopting those of the hospitals with the highest donor rates. In addition, the Massachusetts Health Care Proxy, which all hospitals are required to offer inpatients, could be used as a vehicle to increase the donation rate. Currently, the form asks patients to designate an agent who would have the authority to make all health care decisions for them in the event they become unable to do so. Specifically requesting consent for organ donation on the proxy would legally confirm the patient's wishes in the event of death.

A number of changes could potentially improve upon the use of the RMV as a resource. First, organ donation information should be made available proactively to anyone conducting business with the RMV. Second, aggregate data on license-designated organ donors should be collected via the registry database. This data would be useful in assessing future donation initiatives and policy. Third, the legislature should seriously consider making the OD designation legally binding.

In the coming months, a number of legislative and judicial developments bear watching, including court rulings on the allocation rule challenges by several states, and the possibility of a moratorium on the amended allocation rules. However, as the interested parties compete for their interests, the critical difference for patients continues to be the lack of available organs. Until alternative organ sources become safe and practical, we must improve upon our efforts and continue to work towards the development of effective organ donation policies nationally and locally.

Endnotes

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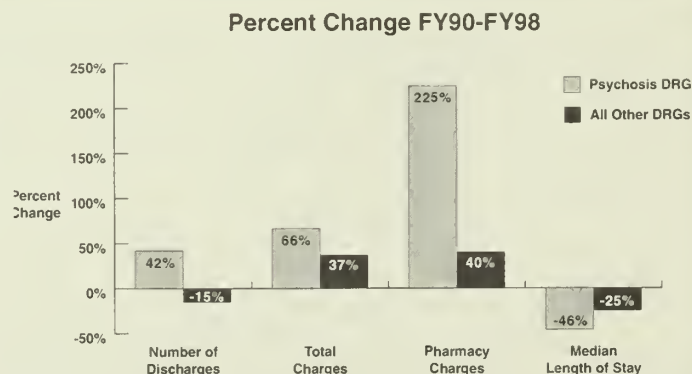
More Information

If you would like to learn more about becoming an organ donor, please contact the New England Organ Bank at 1-800-446-6362.

Did you know?

Psychosis Counters Trend in Declining Admissions

Patient discharges for psychosis (DRG 430) increased 42% while discharges for all other DRGs decreased 15% between FY90 and FY98. In FY98, psychosis accounted for more non-birth-related discharges (26,264) than any other single DRG and accrued the highest percentage of all charges. Its share of charges, especially its associated pharmacy charges, has risen markedly from the beginning of the decade. While the number of discharges with a psychosis DRG has increased, median length of stay has declined more than for all other DRGs.



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HEALTH INFORMATION ONLINE

In a time focused on gathering as much information as quickly and as cost-effectively as possible, one of the most efficient tools is the Internet. As both the quantity of online information and the number of people accessing it have increased exponentially, so have the Internet's uses and influence on health care. A study by HealthCIO.com found that Dr.Koop.com recorded a 726% increase in visitors from January to October 1999.¹ One expert estimated that one in three patients who visits their doctor now brings information gathered from a health care Internet site.²

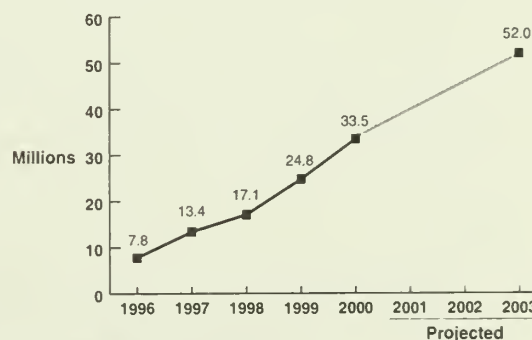
With an explosion in the number of health care world wide web sites and other health care applications online, the influence of the Internet is inescapable. While the innovations of our computer-centric society already result in administrative simplification and cost savings, some Internet applications in health care raise policy issues even before their effects are fully realized. This edition of *Healthpoint* looks at how the Internet affects health care and fuels consumer empowerment, threatens patient privacy, and highlights the limitations of regulatory oversight.

Consumer Empowerment

Current estimates indicate that 33.5 million Americans use the Internet to seek health information (see figure below) and to develop questions and preferences about their care options, formerly impossible without their doctors. While patient education and empowerment is viewed positively by most doctors, a newly educated consumer inevitably changes the historic doctor-patient relationship. Coupled with the existing suspicion many consumers feel toward managed care, this newfound "expertise" may irritate an already tenuous relationship between consumers, providers and payers.

There is growing concern that consumer awareness gained online and through advertising has led to rising medical and drug costs, and will continue to do so. One recent online survey

U.S. Adults Seeking Health Information Via the Internet



Source: InterQual, 2000

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Number 17 April 2000

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found that 79% of all respondents seek out drug information on web sites.³ Many consumers see the Internet as a way to arm themselves with the minimum information needed to navigate the health care industry, but may not be aware of what they don't see on the Internet—cheaper generic drugs or long-proven therapies that would also alleviate their condition.

Accuracy

Currently, consumers and providers have no assurance that information on the Internet is accurate or complete. The Federal Trade Commission has undertaken a number of sting operations to uncover quackery on the web. In 1999, they issued the results of Operation Cure.all, a two day audit of health information web sites which uncovered 800 sites containing promotions for questionable products or services marketed to improve health.⁴ An investigative study of health care web sites published in the *Journal of the American Medical Association* in 1998 found that only one percent of the research posted came from evidence-based sources and 82% of the sites did not list when the information was posted or updated.⁵

However, many consumers feel that for too long the channels for distribution of medical information were controlled by a relatively small group of academic researchers who disdained or ignored efficacious non-Western therapies and conducted clinical trials which omitted large cohorts of the American population. To these observers, the Internet opens new opportunities for obtaining information not subject to the long-standing rules of establishment medicine and its representative journals. In using this new channel of information, consumers should be aware that they may be sacrificing scientific rigor.

The Haves and the Have-Nots

With all the attention surrounding consumer empowerment and e-commerce, it is easy to overlook the fact that not all Americans are able to take advantage of the Internet. In a society which stands alone among industrialized nations in not universally insuring its citizens for health care, how will this latest tool impact its have-nots? The digital divide separates not only the poor from the rest but, very significantly, elders from the rest. Will separating elders, the most frequent users of health care, slow the Internet in reaching maximum effectiveness until a new computer literate generation of Americans become the elderly?

In its 1999 report, *The Future of the Internet in Health Care*, the Institute for the Future found that while about half of all Americans will have access to the Internet either at work or at home by the year 2005, there is a racial discrepancy in the number of homes with Internet connections.⁶ Among all income levels, Internet or e-mail access was available in the homes of 57% of whites but only 38% of blacks, narrowing in households with incomes under \$30,000 to 34% of whites and 19% of blacks.⁷ In January 2000, *Health Affairs* reported that only 15% of the U.S. population age 55 and over is online.⁸ As the health care industry more thoroughly incorporates Internet applications into daily business practice, including contact with patients, provisions must be made for those without Internet access.

Privacy

Perhaps the most important issue surrounding the use of the Internet in health care is ensuring the security of personal medical information online. This concern is not unique to health care but parallels, for example, concerns regarding credit card security during e-commerce transactions. A

recent survey of consumers found that 17% of Internet users do not search health information web sites at all because of privacy concerns, and 89% would not enter personal information on a web site if they knew it might end up in the hands of a marketer.⁹

These concerns may be justified given the results of an investigation into the security and privacy practices of 19 of the nation's most popular health care web sites.¹⁰ This study found that even sites with comprehensive policies and safeguards fail to protect the anonymity and privacy of visitors due to inconsistent enforcement practices, the action of hackers, and linkage to third party sites that do not uphold the same standards. It remains to be seen whether commercial health care sites requiring log-in identification will flourish and whether patients on a large scale will allow their medical information to be stored, exchanged or transmitted online. The health care industry must overcome real and perceived threats to privacy for the Internet to realize its maximum potential effectiveness in this arena.

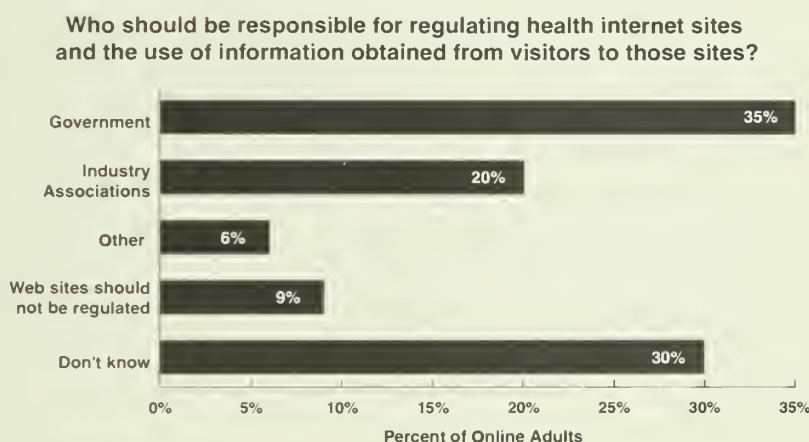
Regulations

The growth of the Internet has increased concern regarding consumer protection in health care. While policy makers discuss whether and how to regulate the Internet, it is important to question whether anyone can regulate a world-wide link that is not controlled by one country, industry or entity (see figure right). While the

Clinton administration's established policy with regard to the Internet has been to encourage self-regulation, its budget proposal for FY01 includes \$10 million for the Food and Drug Administration (FDA) to set up a system to certify that prescription drug web sites comply with federal and state regulations. State

attorneys general also are taking an active role in the fight against online pharmacies by enforcing state statutes that prohibit dispensing prescription drugs by pharmacies not licensed in their state.¹¹ Last year, the National Association of Boards of Pharmacy introduced its Verified Internet Pharmacy Practice Sites (VIPPS) program. VIPPS issues a seal to pharmacy web sites meeting criteria developed by the body to ensure compliance with applicable state and federal regulations.

While these law enforcement efforts may curb some of the illegal sale of prescription drugs across state lines, creating new federal laws will do nothing to prevent companies outside the United States from violating consumer protection measures or selling drugs that have not been subject to stringent FDA clinical trials. The U.S. Customs Service recently joined with the government of Thailand to close down foreign web sites selling prescription drugs to American consumers over the Internet.¹² While many of the drugs hawked are illegal or strictly controlled in the United States, the fact that the same legitimate drugs sold here are more expensive than in almost any other country will continue to motivate Americans to bypass American pharmacies via the Internet. If both national and international efforts are inadequate in overseeing the Internet, is it sufficient



to merely educate consumers that the "buyer beware" principle now applies to something as important as their health and well-being?

Conclusion

As market forces continue to allow and encourage consumers to take a more active role in their health care, policy makers and industry leaders struggle with how they can use these forces effectively without stifling the many benefits of the Internet. Policy makers should actively ensure that the privacy concerns of individuals are thoroughly addressed, establish ways to combat deception and false information online, and subject violators to strong penalties. In addition, consumers must continue to use judgement in assessing the sponsor and content of each health care site they visit. Moving forward, we should explore the uses of the Internet in health care with a sense of both wonder and caution.

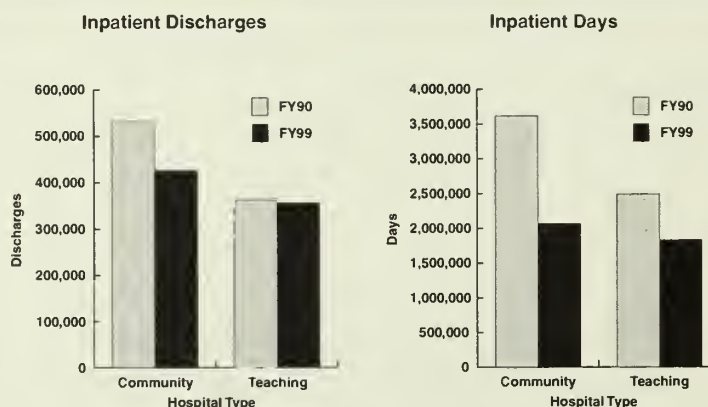
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Did you know?

Teaching Hospitals Have Gained Market Share Since 1990

One way to slow increasing health care costs is by steering patients to the lowest cost site of care appropriate to their condition, such as ambulatory centers and community hospitals, with tertiary hospitals used for specialized care. Since FY90, community hospitals have seen steeper declines than teaching hospitals in both inpatient discharges (20% versus 3% respectively) and inpatient days (43% versus 26%), but still account for the majority of Massachusetts discharges and days.



Source: Massachusetts Division of Health Care Finance and Policy hospital discharge data

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END OF LIFE CARE

Death is the final event that occurs inevitably to all of us, yet improvement in care for dying patients has lagged considerably behind improvement in other types of care. While legislative and judicial developments have helped define the legal framework for end of life (EOL) care, medically, it remains an art negotiated between patient, family and clinician. Written preferences cannot possibly address every eventuality, and other models of care negotiation such as birth plans and informed surgical consents, fall short as models for determining the course of EOL care. No other part of the life cycle is more intrinsically discomfiting and difficult to discuss, and to face, than death.

By 2010, the number of Americans over age 55 will have grown by 25%, and just as baby boomers first put child birth and then menopause on the medical and commercial radar screen, so will they compel society's attention to dying. Already alerted and often dismayed by the death experience of their parents, they will undoubtedly transform this process too. Even the American Medical Association warns the doctors of dying patients that they have only one chance to "get it right" and if they do not, those who watch may worry that their death will be similar.¹ This issue of *Healthpoint* examines issues in current EOL care and policy implications for the way we die.

Current Trends

In 1989, a four-year study began in five U.S. teaching hospitals to facilitate advance directive (AD) planning and patient-physician communication. The project (SUPPORT) found that despite using specially trained nurses to improve communications among caregivers, dying patients and families, patient resuscitation wishes were often unknown, patient preferences misunderstood, aggressive care continued until shortly before death, and patients reported moderate or severe pain during their last three days of life.² These findings stimulated many initiatives, but innovators have found few easy solutions.

Advance Directives

Millions of Americans have signed living wills and power-of-attorney documents, yet these documents can suffer from vagueness, familial disagreement, staff fear of prosecution and physician override (intentional or inadvertent).¹ Even if the AD is completed and filed in the patient's medical record, the AD may not be accessed in a crisis situation such as admission to an acute care hospital.

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Number 18 July 2000

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Optimally, patients create ADs and establish health care proxies in conjunction with their physician and family before a crisis occurs. However, if not previously completed, the hospital or nursing home should make available a facilitator, trained in EOL issues, to promote discussion among the patient, the physician, the family, and the facility to determine the patient's wishes, designate a health proxy, and complete the AD. Ideally, the AD should be modified over time to reflect any change in a patient's condition or wishes.

Pain Management

Effective pain management is a universal goal, yet in most settings we fall far short of the ideal. The hospice adage about pain, "we believe the patient" is not necessarily the rule in hospitals. Barriers to good pain management include pain being under-valued, -recognized, and -reported, inappropriate fears about tolerance and addiction, and fear of government investigation of high dose prescriptions. Most physicians generally prescribe pain medication in lower dosages and at longer intervals than suffice for the terminally ill and thus fail to provide continuous comfort. Furthermore, physicians can objectively measure and treat problems such as high blood pressure, but they must rely on a *subjective* patient report to measure pain. Pain management departments in hospitals provide consultation, but this expertise needs to be more common among primary care physicians. The 1998 report from the Massachusetts End of Life Care Commission recommended that pain be considered "the fifth vital sign" and be monitored appropriately.³ Currently, Congress is considering the Hyde Nickles Pain Relief Promotion Act which would criminalize ordering medicine for the purpose of assisted suicide; hospices fear this bill will further discourage physicians from prescribing appropriately high doses of pain relievers to dying patients. EOL care experts urge the federal Drug Enforcement Agency and Boards of Medicine and Nursing to take the clear position that responsible prescribing for EOL care will not be investigated.

Recommendations from the 1997 Report of the Massachusetts Pain Commission resulted in comprehensive revision to state narcotic regulations and formal adoption of the American Pain Society's *Quality Improvement Guidelines for the Treatment of Acute and Cancer Pain* which include promptly treating pain, and charting and displaying patient-reported pain.⁴ The Massachusetts Board of Registration in Medicine has also established guidelines for treating patients with chronic pain unrelated to cancer.

Hospice

Hospice utilizes practitioners well versed in pain management and psycho social support who address the physical, emotional, social and spiritual needs of the patient while attending to family and caregiver needs. In 1997, 7,708 patients died (primarily from cancer) under hospice care in Massachusetts; that year 13,796 residents died of cancer overall. For patients to receive

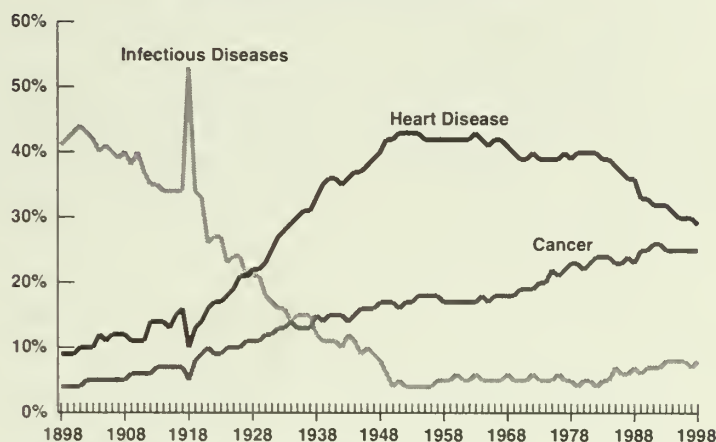
the Medicare hospice benefit, they must sign a statement agreeing to forego treatment except for comfort measures and a physician must stipulate a survival prognosis of less than six months. Both the prognosis determination and its acceptance are barriers to hospice use especially by end stage chronic disease patients with a less predictable disease course. Patient

Site of Death, Massachusetts Residents

Site of Death	Year			
	1992	1994	1997	1998
Hospital	57.9%	52.6%	47.2%	46.8%
Nursing Home	19.2%	23.9%	29.4%	29.4%
Home/Hospice	21.2%	22.0%	22.1%	22.4%
Out of State	1.7%	1.6%	1.4%	1.4%

referral to hospice currently occurs close to time of death with local hospices reporting a median length of stay of 2-3 weeks. This compromises the quality of care provided by turning it into crisis intervention. Also, since the greatest patient costs occur during the first and last days of hospice care, the financial viability of some hospices is jeopardized with fewer inexpensive middle days to offset high intensity days.

Trends in Deaths from Selected Causes, Massachusetts (1898-1998)



Measurement

Massachusetts insurers, hospitals and nursing homes routinely survey patients to determine satisfaction with care delivered, but presently all deliberately exclude next of kin (NOK) of deceased patients. Thus, health care provider performance is not measured at a time when a patient has often received medicine's most intense efforts. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has standards for measuring EOL care in hospitals in several domains but does not mandate surveys. The National Committee for Quality Assurance (NCQA) has no standards regarding EOL care by HMOs, probably reflecting HMOs' relative lack of involvement to date in elder care nationally.

No established instrument exists for surveying dying patients or their NOK, but the Picker Institute, in conjunction with the Center for Gerontological Research at Brown University is now developing such a survey. The survey, available for general use in 2001, will identify opportunities for improving EOL care by integrating the patient's perspective on the care provided.

It has been argued that surveying NOK would be insensitive and result in misplaced reactive ratings from grieving family members. While it is true that patients rate their care roughly in proportion to the happiness of the outcome (overall, maternity patients rate their hospital stay better than other patients, for example), it would behoove providers to believe and to act on their ratings, not discount them. Of the more than 700 hospitals nationwide that survey patient satisfaction, only one has included NOK but discontinued doing so after their satisfaction ratings dropped.

Provider Education

Physicians cite EOL care as an important aspect of their work about which they wish they had learned more in training.⁵ The University of Massachusetts Medical School mandated their previously optional EOL course for medical students but only recently has the accrediting body for medical education instituted a similar mandate for all medical students. Harvard Medical School, the Massachusetts-based National Center for Death Education, and the Massachusetts Extended Care Federation are all establishing courses in palliative and EOL care issues designed to train trainers.

The Massachusetts Compassionate Care Coalition (a coalition of approximately 40 health organizations) has adopted a different approach to meeting EOL care needs. Five Coalition members are studying a La Crosse, WI project which implemented an AD education program

resulting in 85% of the 504 decedents in the study population completing ADs (95% of which were in the decedent's medical record), almost all of whom requested that treatment be forgone as death neared. Treatment was forgone in 98% of deaths. The Coalition hopes to transplant its success to Massachusetts.⁶

Policy Implications

Massachusetts legislators have proposed a 15-member Commission on EOL care that will recommend improvement and expansion to EOL services by March 1, 2001. The ultimate goal is to develop an approach in which the settings where people die are interconnected and clinicians provide care in accordance with patients' wishes. Congress could expand Medicare hospice eligibility beyond the six-month survival criteria for chronic and terminally ill patients requesting hospice-like services where survival prognosis cannot be determined. Health care policy makers could require clinical teaching programs to provide EOL care training. Such requirements might be tied to the receipt of Medicare or state funds used to support medical training programs. Finally, Massachusetts could mandate that NOK be surveyed by licensed facilities to ensure accountability in areas such as pain management, adherence to ADs and other EOL care services. Only under a system of mandated surveying could consumers measure satisfaction across providers and providers be compared fairly in receiving what might well be a drop in ratings.

Endnotes

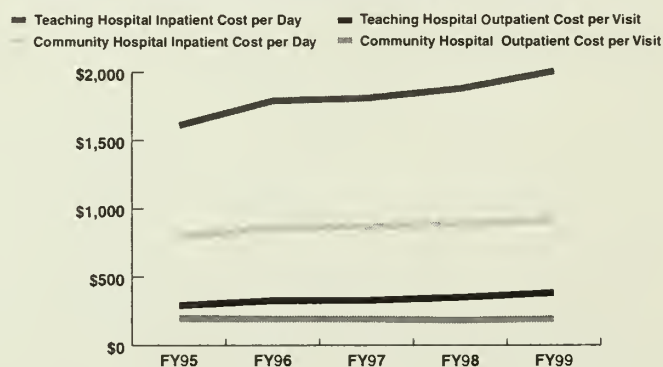
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Did you know?

Severity Adjusted Costs Differ at Teaching and Community Hospitals

Per diem inpatient costs at teaching hospitals are substantially higher than those at community hospitals even when adjusted for severity. However, there is a much smaller difference in costs between their outpatient visits. This means that teaching hospitals and community hospitals differ far more in their inpatient practices than in their outpatient practices. Furthermore, teaching hospital costs for inpatient care rose more steeply than at community hospitals while outpatient care costs per visit at community hospitals actually dropped between FY95 and FY99.

Case Mix Adjusted Inpatient and Outpatient Costs per Day/Visit



Source: Massachusetts Division of Health Care Finance and Policy hospital discharge data

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MENTAL HEALTH PARITY: WHAT WILL IT BRING MASSACHUSETTS?

emphasizing the need for comprehensive behavioral health care coverage. The report estimates that one in five American adults endure a diagnosable mental illness in any given year, but less than a third of them seeks treatment. It also estimates that mental illness costs society about \$200 billion annually in direct and indirect expenses.¹ Similarly, the Massachusetts Department of Mental Health reports that 15.22% of adult residents have a diagnosable mental illness in any given year.² This belated public attention to mental illness and its societal impact has lead researchers and legislators to scrutinize the comprehensiveness of behavioral health benefits, including the 1996 federal parity legislation.

While the objective of parity is to ensure that payers provide the same standard level of benefits for behavioral health and substance abuse as for physical health, the law has many shortcomings. It neglects to mandate provisions for substance abuse treatment, exempts small firms, and fails to require plans without mental health coverage to offer such benefits. Concurrently, primary care physicians (PCPs), pharmaceuticals, and managed care carve-outs are each playing an increasing role in the treatment of mental illness, leading us to ask: How relevant is parity now? With the recent enactment of full parity legislation in Massachusetts, this *Healthpoint* explores the impact and relevancy of the new law as it affects payers, providers and residents of the Commonwealth.

Mental Health Legislation

The 1996 Federal Mental Health Parity Act mandates that all employers offer equivalent annual and lifetime monetary coverage for behavioral and physical health needs. A lesser-known "sunset" provision, included to protect employers from unanticipated long term costs, automatically terminates the federal law on September 30, 2001.³ With states left to fill in the gaps, Massachusetts passed one of the most comprehensive mental health parity laws in May 2000.

Who Is Covered and Who Is Exempt?

The Massachusetts mandate requires complete compliance for all members of HMOs, employer group plans and non-group individual plans by January 1, 2001.

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Number 19 October 2000

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Smaller employers must comply by January 1, 2002. Under the 1974 Employee Retirement Income Security Act (ERISA), states cannot regulate employer-provider health plans, exempting most self-insured employers, many of whom voluntarily comply with state mandates. While MassHealth (Medicaid) clients and state prisoners are also exempt from state mandates, Medicaid has historically provided comprehensive mental health and substance abuse benefits.

What Is Covered?

The Massachusetts mandate requires employers to provide full parity for “biologically-based” brain disorders classified in the Diagnostic and Statistical Manual-IV (DSM-IV), such as schizophrenia and major depression. It provides full parity for substance abuse only when co-occurring with a mental illness. It requires insurers to maintain the 60 day inpatient care minimum mandated under current law and to triple the number of outpatient visits to 24 for all non-biologically based psychiatric disorders in the DSM-IV. Mental health assessments and visits made for monitoring medications are covered in full and are not considered part of the outpatient visit allotment. Furthermore, the mandate establishes unlimited outpatient visits for children under age 19, if their disorder is even at risk of interfering with normal cognitive and social development.

From Paper to Practice: Will Parity Have an Impact?

Despite the comprehensive nature of the Massachusetts parity law, two divergent trends in mental health services could impact its intended effects.

Roughly 50% of depressed patients are treated by primary care physicians (PCPs), while only 20-30% of these patients seek concurrent treatment with a behavioral health specialist.⁴ The prominent role of PCPs in treating mental illness is troublesome. One concern is the difficulty in accurately diagnosing less acute mental disorders and symptoms of substance abuse. A study of HMO primary care patients treated for depression found that PCPs accurately diagnosed only 50% of all depression-related cases.⁵ PCPs are also prescribing about 66% of all psychotropic drugs⁶ and one study of a national managed care organization’s antidepressant utilization patterns indicates that PCPs prescribe 77% of all antidepressants, with only 42% of these prescriptions based on a documented primary or secondary diagnosis of depression.⁷

It is unknown whether the increased role of PCPs in the treatment of mental disease is due to patient preference (less stigma, more familiarity), limited availability of specialists, capitation incentives or other reasons, yet it almost certainly impacts the quality of care (especially vis a vis psychotropic drug prescriptions). It should be noted that in Massachusetts, HMOs generally do not require referrals for mental health services and it is not known whether the national trend toward increased PCP involvement in treating mental illness occurs here where specialists are plentiful. To discourage this trend from materializing here, purchasers could adopt the Group Insurance Commission (the state employee and retiree benefits purchaser and manager) policy, which only covers mental health services, including psychotropic drug prescriptions, when rendered by a licensed behavioral health specialist. Since visits to a PCP whether for mental or physical illness are unlikely to be limited, parity here appears moot, but a concern over quality is not.

At the same time, the past decade saw a significant increase in managed care carve-outs, a separate vendor or Managed Behavioral Health Organization (MBHO) that provides mental health and substance abuse services. In contrast to concerns surrounding PCP care, carve-outs provide mental health services from a network of licensed behavioral health specialists in a concerted effort to pro-

vide quality, specialized care. MBHOs could indirectly thwart the quality of care strived for in the parity legislation, however, through lower reimbursement rates, possibly resulting in fewer experienced specialists participating in the network. Harvard Pilgrim Health Care, for example, recently contracted with MBHO Value Options to manage its behavioral health services, paying them a capitated monthly per-member fee. Value Options subsequently decreased reimbursement rates for psychiatrists and psychologists, but increased payments for social workers and other Masters level professionals, and stated its intention to increase the use of group therapy.

While these modifications in service delivery may not have a deleterious effect on care, it will be important for managed care organizations (MCOs) to evaluate the carved-out services and monitor member satisfaction. MCOs must also be vigilant that the use of a capitated incentive system with for-profit MBHOs does not lead to inappropriate reductions in referrals, hospitalizations or lengths of treatment, thereby indirectly undermining parity by compromising quality.

Direct Costs of Parity

Several analyses on the costs of mental health coverage have been published. Despite estimated cost increases (ranging from 2-4%) under federal parity, the US General Accounting Office (GAO) reported that only 3% of employer respondents experienced an increase in overall health care costs due to parity compliance.⁸ It is widely surmised that many employers simply substituted visit restrictions or increased copayments, deductibles, out-of-network charges and out-of-pocket contributions for the prohibited dollar cap. The cost impact of Massachusetts' parity law on premiums is projected to be similar if not lower than national estimates and significantly less than the projected individual premium increases by payers due to the large HMO penetration in the Commonwealth and anticipated cost-containment measures likely to be adopted by employers to offset parity-related expenses (see table above).⁹

An Actuarial Analysis of the Massachusetts Mental Health, Alcoholism and Chemical Dependency Parity Law		
Payer Type	Percent Increase in Health Plan Premium Due to Comprehensive Parity	Total Mental Health and Substance Abuse Claims Costs Per Member Per Month (PMPM)
HMO	1.6%	\$6.02
PPO and POS	2.5%	\$8.09
Managed Indemnity	3.2%	\$12.31
Fee-for-Service	3.9%	\$15.26
Net Market Impact	1.0%	\$1.41

Indirect Costs of Parity

The cost of mental health coverage must be contrasted with the cost of non-treatment or standard treatment. One analysis associated a \$79 billion loss to the US economy in indirect costs, with the majority of these costs (\$63 billion) attributed to lost productivity.¹⁰ Mental illness has a low mortality rate, but if untreated, can severely impinge on one's productivity and health over a life span. Similarly, the World Health Organization's Global Burden of Disease study reported that five of the top ten leading causes of disability and premature mortality are psychiatric and addictive mental disorders, accounting for over 15% of the overall burden of disease from all health related causes.

When looking at the burden placed on Massachusetts specifically, the cost can be illustrated in part by reviewing the prevalence of mental health services sought through general acute hospitals. In 1999, seven percent of total acute hospital discharges in the Commonwealth had a primary diagnosis

of psychiatric or substance abuse, with the psychoses diagnosis (DRG 430) consistently ranking first or second in both percent of discharges and percent of charges among all acute hospitalizations.¹¹ The burden of such care is even more striking within the uninsured population, where 11.7% of patients using the Uncompensated Care Pool to finance their hospitalizations were admitted for mental disease and disorders, second only to problems with the circulatory system.¹²

What Can We Expect for the Future?

In 1999, President Clinton directed the Office of Personnel Management to achieve "full parity," including substance abuse in the Federal Employee Health Benefits Program (FEHBP) by 2001.¹³ Both houses of the 106th Congress have introduced such legislation prohibiting numerical limits on inpatient and outpatient visits, repealing the 1996 exemption for employers who report an increase in their premiums greater than one percent and revoking the "sunset" provision.

By virtue of passing comprehensive parity legislation, Massachusetts is uniquely positioned as a pioneer for the mentally ill. Now, the Commonwealth must seize the opportunity to evaluate the impact of parity on payers, providers and patients by following the trends in costs, accessibility and utilization of mental health services. The actual success of parity will depend on its evolution from paper to practice.

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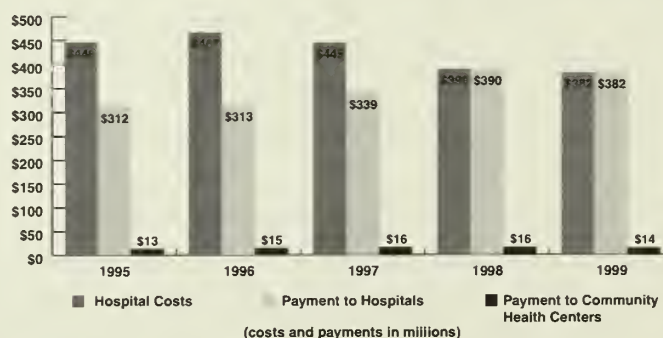
Did you know?

CHCs and Hospitals Are Paid Differently for Uncompensated Care

Since 1992, the Uncompensated Care Pool has paid community health centers (CHCs) for the uncompensated care they provide. Unlike hospitals, the Pool pays CHCs based on a standard fee schedule. Also unlike hospitals, CHC payments from the Pool are not reduced when there is a shortfall in Pool funds, therefore, there is no difference between allowable costs and payments for CHCs as there is for hospitals.

Beginning in 1998 the Pool was funded adequately to cover all charges to it. Prior to this time, uncompensated care charges were greater than the dollars available to fund such care, resulting in a shortfall.

Allowable Cost and Payment to Hospitals and CHCs for Uncompensated Care in Massachusetts (1995-1999)



Note: These numbers have not been adjusted for inflation.

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Sources: Uncompensated Care Pool, FY99 Annual Report, March 2000 and "Community Health Center Payment Voucher Supplemental Form," Division of Health Care Finance and Policy.

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Welcome to
the 20th issue
of **Healthpoint!** 20

The *Healthpoint* series started in 1996 as a quarterly issue brief for policy makers and has grown dramatically in popularity and readership. We welcome thoughtful suggestions that will ensure the value of future issues. To share your comments, suggest a topic, or request back issues, please contact the DHCFP Office of Communications, (617) 988-3125 or write to us for your interest.

GENETIC TESTING: ITS LIMITATIONS AND PROMISE

Until recently, genetics has played a relatively minor role in clinical medicine, primarily affecting the small segment of the population with a disease exclusively tied to a chromosomal abnormality or mutation. Genomics or the "new" genetics has uncovered genetic contributors to many common diseases and scientists predict that as more becomes known, genetic findings will inform numerous diagnostic, reproductive and therapeutic decisions. However, unlike the identified gene mutations that solely cause cystic fibrosis or sickle cell anemia, genomics uncovers predisposition, not inevitability, and this distinction has tremendous implications for how testing is used and how results are acted upon.

Scientists now believe that nine of the 10 leading causes of US mortality (injury excluded) will be shown to have some genetic component (see table below). Therefore, the political, ethical and social implications of genetic testing that have been the purview of relatively few families and their medical specialists will soon affect many of us and our primary care providers. This issue of *Healthpoint* examines genetic testing, its implications, as well as its limitations in predicting our individual medical futures.

Genetic Tests

A genetic test is an "analysis of chromosomes, DNA, RNA, genes and/or gene products to determine whether an alteration is present that is causing or is likely to cause a specific disease or condition."¹ Genetic tests are recommended to determine definitively whether one has a disease, to diagnose the exact type of disease one has, or to determine the likelihood of one to develop or pass on a disease. The complexity of issues raised by testing leads most medical providers to recommend that the patient speak with a genetic counselor before and after testing. The genetic counselor helps evaluate risk and clarify treatment options especially amidst the uncertainty

The 10 Leading Causes of Mortality in the US

	Percent of Deaths in 1998
1. Heart Disease	32.0%
2. Cancer	23.2%
3. Stroke	6.8%
4. COPD	4.8%
5. Injury	4.2%
6. Pneumonia/Influenza	3.9%
7. Diabetes	2.8%
8. Suicide	1.3%
9. Kidney Disease	1.1%
10. Chronic Liver Disease	1.1%

of testing for predisposition. These sessions are not always covered by insurance despite the widespread belief that they are essential to informed and thoughtful decision making.

Genetic tests can be performed on a particular patient, a population (newborns), or those at risk for passing on a disease (a carrier). Predictive tests are performed on individuals determined to be at high-risk by their family history for developing a hereditary disease. These tests can be important for one found to have a genetic predisposition to a disease for which screening (i.e. mammography) or treatment exists. For example, for women who have a high preponderance of breast or ovarian cancer in their family, learning that they may have a genetic predisposition to the disease would alert them to the need for frequent screening. More aggressive interventions such as chemoprevention or even prophylactic surgery exist, but present painstaking choices to a patient who doesn't know whether she will in fact ever develop the disease. On the other hand, the vast majority of these cancers are thought to have other causes (smoking, poor diet, exposure to carcinogens, etc.), so one couldn't take complete comfort from a negative genetic test or abandon healthy living or regular screenings.

Although the popular media's focus has been on predictive testing, experts estimate that it is diagnostic testing that accounts for 90% of all genetic tests currently performed. These tests diagnose a genetically related disease in a person exhibiting particular symptoms or they identify the genetic makeup of one's previously identified condition to target a treatment regimen. Insurance coverage for predictive tests varies while diagnostic tests are generally covered. Many insurers have no written policy on genetic testing, determining coverage on a case-by-case basis.

Testing to Inform Reproductive Decisions

Carrier testing is performed for family planning purposes prior to conception to determine whether an individual carries (and therefore may pass on) one copy of an altered gene for a particular disease. Tay-Sachs carrier testing, begun in the 1970s among the higher-risk eastern European Jewish population, has proven successful in significantly reducing the number of Jewish babies with this disease conceived by two carriers, thus lowering the incidence of this fatal disease. Other diseases also occur in specific ethnic populations at higher frequency than in the general population, so primary care physicians should suggest and make available carrier testing when applicable.

Since there is no carrier test (which would be preferable) for many birth disorders, prenatal diagnostic genetic testing is recommended for those at high risk. Amniocentesis, approved by the Federal Drug Administration (FDA) in 1967, is one procedure used especially in pregnant women over age 35 to test for a variety of abnormalities, most famously Down's syndrome. When a test reveals a significant anomaly, parents face an emotional decision—to terminate the pregnancy or to prepare for the birth of a child with special health care needs. As a result of prenatal screening, amniocentesis and subsequent pregnancy termination, the number of babies with significant anomalies born to older mothers has decreased.

Newborn Screening

Each state requires its newborns to be tested for some number of genetic disorders, making newborn screening the most common application of genetic testing today. Massachusetts' newborn screening program, established in 1962, is one of the most comprehensive in the country, screening newborns for 10 disorders plus currently, an additional twenty through an optional pilot program. For a disorder to be included in the required screening program, the test for it must be reliable and

the disorder treatable through early medical intervention. Screening at birth is crucial for the small group of babies with rare diseases for whom immediate treatment prevents mental retardation, disability or even death.

The Massachusetts Genetics Program

In 1980, Massachusetts became the first state to recognize the increasing importance of genetics with the establishment of the Massachusetts Genetics Program within the Department of Public Health. The Program has been responsible for facilitating the development, delivery, and appropriate utilization of high-quality, family-centered, community-based, culturally and linguistically appropriate genetics services and public policies. Today, the Program is conducting a statewide genetics needs assessment and strategic planning process in order to plan for its expanded role as the field of genetics extends its reach to many more of us.

Insurance Discrimination and Privacy

As the number of genetic tests available increases and one's disease predispositions become more accurately identified, there is heightened concern about potential discrimination in employment and insurance decisions. State laws on genetic information privacy and discrimination were first enacted in the 1970s, but these laws were disease-specific and thus narrow reaching. Many states have enacted broader protections; Massachusetts became the most recent state to do so in August 2000. This new law bans insurance and employment discrimination based on genetic information and includes provisions on privacy and informed consent prior to testing. Today, thirty-three states prohibit discrimination for health insurance based on hereditary disease factors, twenty states require the insured's consent to disclose genetic information and 22 states prohibit employment discrimination based on genetic information.²

In addition to state-level activity in the genetics arena, federal legislative action has been taken to ensure a national standard of protection and to reach the self-insured exempted from state law. The 1996 Health Insurance Portability and Accountability Act prohibits an insurer administering a group plan from using genetic information to deny coverage or increase premiums. In addition, the Secretary's Advisory Committee on Genetic Testing was chartered in 1998 to advise the Secretary of Health and Human Services on issues raised by the development and use of genetic tests.

Policy Concerns

In recent years, many commercial developers of genetic tests have patented both the tests and the genes upon which they are performed, sometimes charging royalty fees per test and requiring facilities to pay a fee for designation as a testing site. The biomedical industry insists that the practice of patenting is fundamental to promote and protect research and development. Opponents of gene patenting counter that this will encourage companies to either prematurely introduce genetic tests to recoup investment more quickly or inappropriately broaden the definition of an at-risk population in an effort to increase its utilization. For example, the company which holds the patent for the breast cancer genetic test doesn't exclude from its testing criteria women without a family history of breast or ovarian cancer despite widespread medical agreement that it is women with a high prevalence of those diseases in their family who are most likely to have a genetically linked cancer.³

Another area of policy concern is that some testing facilities are already advertising directly to consumers, a strategy mimicking the pharmaceutical industry. Since 1997 when the FDA relaxed

its advertising rules, there has been a huge increase in pharmaceutical advertising and subsequent consumer demand for name-brand drugs. Direct to consumer advertising for gene testing might dramatically increase our medical costs if those who seek it are primarily the "worried well" rather than those at high risk. Therefore, policy makers should strongly consider prohibiting the genetic testing industry from following the same unfiltered path to consumers that the pharmaceutical industry now enjoys.

The Future of Genomics

The rapid pace of genetic discovery has been driven in part by the 1990 launching of the Human Genome Project, an international public and private collaborative effort to identify the approximately 100,000 genes in human DNA. It is anticipated that its findings will not only increase the number of genetic tests available but lead "to a new era of molecular medicine characterized less by treating symptoms and more by looking to the most fundamental causes of disease."⁴ The Project is expected to spur advancements in the emerging field of pharmacogenomics, "the study of how an individual's genetic inheritance affects the body's response to drugs."⁵ It is anticipated that physicians will be able to prescribe drugs designed to work for an individual's specific gene mutation, thereby leading to a more efficient system of prescribing with fewer adverse drug reactions. While this application may be many years off, there is no doubt that in the meantime the impact of genetics will continue to grow in all areas of clinical medicine.

Endnotes

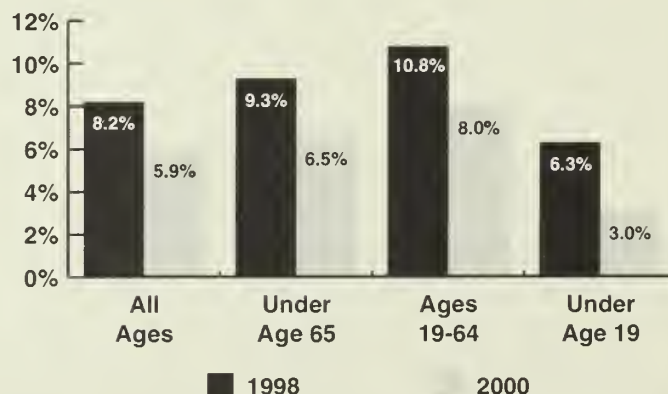
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Did you know?

Fewer Individuals in Massachusetts Are Uninsured in 2000

In 1998, the Division of Health Care Finance and Policy initiated a statewide survey of the health insurance status of state residents, and repeated it in 2000. The results indicate that approximately 9.3% and 6.5% respectively of all non-elderly Massachusetts residents were uninsured at the time of the interviews. In both years, the largest group of uninsured individuals were ages 19-64. Those under age 19 showed the greatest rate of decrease between 1998 and 2000, most likely due to the State Children's Health Insurance Program, S-CHIP, a federal expansion but one inspired by a Massachusetts reform, Chapter 203 of 1996.

Percent of Uninsured by Age Group



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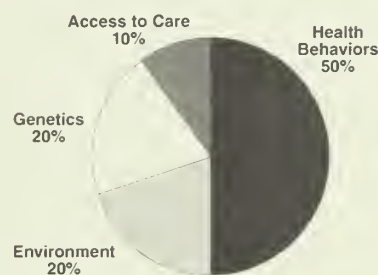
CHRONIC ILLNESS—ACUTE SYSTEM

The current paradigm of health care delivery dates back to an era in which the typical patient suffered from an acute, usually infectious, illness. Today, however, almost half of the United States population suffers from one or more chronic diseases—conditions that are prolonged, do not resolve spontaneously and are rarely cured completely. Accounting for more than three-quarters of direct medical expenditures,¹ these illnesses cause the majority of deaths in the United States.² Effective care of chronic illness requires management that is multifaceted and often of lifelong duration. In contrast, acute illness usually calls for discreet and time limited medical intervention. Although the health care delivery system responds relatively well to the medical needs (as narrowly defined) of chronically ill patients, it has not evolved to encompass the additional components of care that these patients need. This issue of *Healthpoint* examines this disparity and its implications for health care in Massachusetts.

Recognizing that modifiable behaviors account for the majority of morbidity today, treatment guidelines for most high prevalence chronic diseases call for some combination of medical intervention and monitoring, behavior change, and adherence to long-term pharmaceutical therapy. The goal of treatment is to improve patient functioning and quality of life, with the patient called upon to assume responsibility for day-to-day management of the disease.

Research has shown that for many patients, lack of support for behavior change and adherence to medication regimens prevents medical therapies from achieving their maximum benefit. Highly Active Anti-Retroviral Therapy (HAART) for HIV epitomizes the complicated, long-term pharmaceutical regimens increasingly characteristic of disease treatment. While HAART has produced dramatic improvement in mortality and a decline in opportunistic infection rates among HIV-infected patients, the long-term success of these drugs is contingent on full viral suppression. In clinical trials, between 80% and 90% of patients receiving HAART achieve and maintain undetectable viral loads. Yet, in clinical practice, less than 50% of patients achieve this goal. The major reason for this apparent difference in drug

Determinants of Health³



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Number 21 April 2001

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efficacy is medication nonadherence.⁴ But difficulty persevering with the demands of a therapy is not unique to HIV. Rather, it is the norm for a range of chronic diseases including congestive heart failure (CHF) and hypertension.

Medication Compliance Rates for Selected Illnesses⁵

Various medications for diabetes and CHF	69%
Antihypertensives	53%
Antipsychotics for schizophrenia	42%

These statistics reflect the challenge of drug adherence, a single component in a repertoire of skills and behaviors necessary to manage chronic illness. In conjunction with medical treatment, however, consistent

self-care lessens the rate of serious complications—without it, medical treatment is only partially successful at best. The diabetes self-care checklist below illustrates the breadth and complexity of these tasks and shows why learning and adopting these behaviors is far from easy.

Although advances in biomedical research receive more public attention, there is a growing body of knowledge about successful behavior change and promotion of self-care within the context of chronic illness. Experts have identified the following components as essential:

Collaborative Definition of Problems

Problems identified by patient are addressed in concert with physician diagnosis.

Targeting, Goal Setting and Planning

Patient and provider focus on a specific problem, set realistic objectives, and develop an action plan for attaining those objectives in the context of patient preferences and readiness.

Creation of a Continuum of Self-Management Training and Support Services

Patient has access to services that teach skills needed to carry out medical regimens, guide health behavior changes, and provide emotional support.

Active and Sustained Follow-Up

Patient is contacted at specified intervals to monitor health status, to identify potential complications, and to reinforce progress in implementing the care plan.⁷

Applying Theory to Practice

While Massachusetts has several well known programs addressing the intimate connection between stress and physical health, these programs don't address the gamut of behaviors exacerbating chronic illness. As discrete programs or institutes, they fall outside the realm of routine health care. Moreover, participation in and insurance coverage for these programs is based on clinical evidence of disease rather than the upstream goal of disease prevention. The situation in Massachusetts is not unique. In January, the Washington-based Center for the Advancement of Health released a Robert Wood Johnson Foundation-funded report, *Health Behavior Change in Managed Care*, which found that managed care plans' integration of strategies to help people change lifestyle behaviors "is limited and piecemeal." Following interviews with HMO medical directors, the center found that

Diabetes Self-Care Checklist⁶

- Monitoring blood glucose
- Taking medication (including dosage-adjustment)
- Planning meals
- Exercising
- Managing complications
- Dealing with special situations (sick days, management of high and low blood sugars)
- Participating in preventive care (eye care, foot care, dental care)
- Communicating with health professionals
- Scheduling and attending appropriate monitoring and follow-up care visits

plans' offerings in behavioral change often are passive and fragmented, that access tends to be tied to a documented medical condition rather than to disease prevention, and that when offered, such programs usually require out-of-pocket expense to members.⁸

While there is general agreement on the importance of educating and supporting the chronically ill patient, and even some knowledge of how to do that effectively, the health care delivery system has not evolved to do this actively. Indeed, payer, provider and patient inadvertently sustain and reinforce a narrow medical approach to illness. Behavioral regimens are harder to quantify and evaluate than clinical interventions. The benefits of behavioral change are incremental, with any cost savings from risk reduction accruing far in the future. This problem of delayed cost benefit is as much a challenge for public payers as for private.

It is inefficient to use a physician's training or time to provide the kind of ongoing support that most people need to comply with long-term pharmaceutical regimens or dramatic behavior changes. For this type of help, nurse practitioners, physician assistants, social workers, pharmacists and in some cases peers, are a logical and more cost effective choice. However, broad acceptance and utilization of allied health professionals in this country generally has not occurred outside of three specific settings: when doctors are in short supply, when individuals have intractable conditions, and in general pediatric care. We can look to pediatric care as a model in particular because it is an example of a collaborative care approach applied to primary care in a general population.

Reasons for widespread use and acceptance of multidisciplinary staffing in pediatrics include:

- high volume of visits
- high demand for child guidance/parental education
- recognition of the need for collaboration with behavioral and developmental care providers such as psychologists, nutrition specialists, counselors, etc.
- emphasis on wellness and preventative care through check-ups and well child visits
- historic link to the public health system, e.g. vaccination practices⁹

Integrated care teams have great potential for the adult population with modifiable health risks since effective management and prevention of chronic illness share many of these same attributes.

Challenges for Massachusetts

Ironically, Massachusetts' supremacy in tertiary medicine has been a barrier to acceptance of a more collaborative, multi-dimensional approach to care. Massachusetts consumers have grown accustomed to seeking "the best of the best," as they define it, without realizing that what they might need to help manage their illness is not necessarily best delivered by the same teaching hospital specialist who diagnosed and stabilized their condition. Teaching hospitals and specialists are abundant here, and in the absence of generally agreed upon quality indicators, technically oriented medical care delivered by physicians is perceived as "better" than less sophisticated, though often more appropriate, therapies and regimens.

At the same time, Massachusetts has unique attributes conducive to improving the system of care for chronic illness. Massachusetts has the highest managed care penetration rate in the country, coupled with a high degree of consolidation in the HMO market. Our state also has a strong and relatively well-funded public health system. Three years ago, payers worked with each other and with government to transform the delivery of preventative care. The chief medical officers of Tufts Health Plan, Harvard Pilgrim Health Care, Fallon Community Health Plan, Neighborhood Health Plan, and Blue Cross Blue Shield of Massachusetts formed their own separate 501(c)(3) charitable

organization, the Alliance for Healthcare Improvement. This group develops preventive care programs endorsed by all five health plans and the Massachusetts Department of Public Health, reducing duplication, improving cost-effectiveness, and reinforcing a single message.¹⁰

Massachusetts took an additional step forward last year by passing legislation (albeit the 36th state to do so) requiring insurance companies to cover diabetic supplies and outpatient education and counseling for diabetes patients. The Diabetes Cost Reduction Act mandates insurance coverage for much needed self-care and disease management resources for people with diabetes.¹¹

Although a mandated benefit can be a powerful tool for increasing access to vital services, it applies only to a limited population and is a disease by disease approach to a problem requiring a systemic solution. Ultimately, transforming the health care system to address the demands of chronic illness requires action across community, organization, practice and patient lines.

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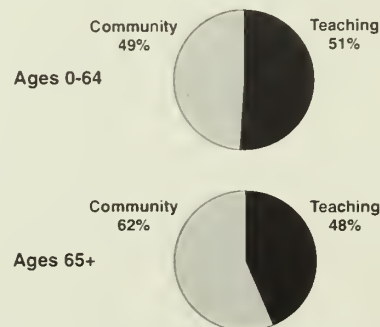
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Did you know?

Younger Patients Are Choosing Teaching Hospitals

Today, despite the fact that the hospitalized elderly almost always require more complex care than younger hospitalized patients, they use community hospitals for more of their care than do younger patients. The decade from 1990 to 1999 saw community hospital use remain constant for those over age 65 but dramatically decline (32%) for those ages 0-64. Use of community hospitals as a proportion of *total* hospitalizations has decreased in both age groups however, indicating that while the trend is to favor higher cost teaching hospitals, younger patients are migrating to them more rapidly. The increased reliance on teaching hospitals by Massachusetts residents, particularly for primary and secondary care, has added to the fiscal crisis of our health care system. Care provided by teaching hospitals is typically more expensive than comparable level care provided by community hospitals.

Distribution of Hospital Discharges by Patient Age and Hospital Type, 1999



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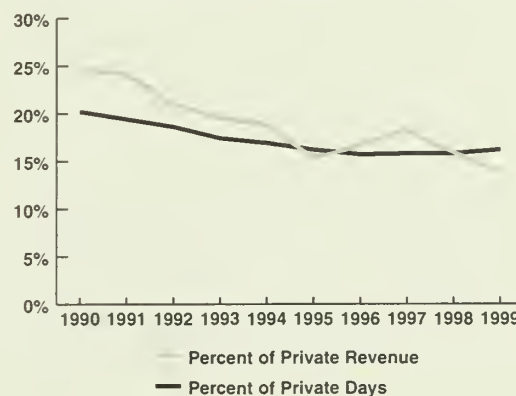
EMERGING TRENDS IN LONG-TERM CARE

Historically, nursing homes have been the main provider of long-term care for the elderly, but in recent years the array of long-term care settings has expanded dramatically. Consumers increasingly receive services in assisted living facilities, adult day health programs, and their own homes. While these changes have generally benefited the consumer, they have altered the face of the nursing home industry. Alternate settings, most notably assisted living facilities, have been successful at attracting private paying elders, formerly a key source of revenue for nursing homes. This issue of *Healthpoint* examines recent trends in nursing home use, the effect of changing market dynamics and future financing of long-term care.

Healthier and Wealthier Seniors Are Choosing Assisted Living

A recent study of data from the 1995 National Nursing Home Survey showed an 8.2% decline in the ratio of persons ages 65 and over residing in nursing homes between 1985 and 1995.¹ This same study also noted the decline in the proportion of patients paying privately for their care—44% in 1985 to 28% in 1995. Similar dramatic changes occurred in Massachusetts. Between 1990 and 1999, the population of Massachusetts residents ages 65 and over increased 5%, but the total number of nursing home days declined 3%.² Furthermore, there was a decline in the proportion of privately paid patient days in Massachusetts nursing facilities, from 20.2% in 1990 to 16.2% in 1999 (see figure right). Even more dramatically, the percent of revenue from private sources declined a startling 43.7% from 24.5% in 1990 to 13.8% in 1999.³ So, as nursing home use has declined overall, there has been an even steeper decline in the share of private paying patients. These patients are important to nursing homes, in large part because they usually pay full charges for their care, unlike the Medicare and Medicaid programs which typically pay less for the patients they cover.

Percent of Private Days and Revenue for Massachusetts Nursing Homes by Year



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Number 22 July 2001

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Seniors who even ten years ago probably would have entered a nursing home now can often choose a less institutional alternative. In particular, people who once would have paid privately for nursing home care (usually wealthier patients who are less frail than average) are now more likely to reside in assisted living facilities. Growth in the assisted living market has been tremendous. In 1990, there were fewer than 30 assisted living facilities in Massachusetts. Today, there are 151 such facilities with nearly 9,000 residence units.⁴ Assisted living facilities differ from nursing homes in several important ways. First, assisted living does not provide any of the skilled nursing supervision that nursing homes do.⁵ Assisted living offers only supportive services to elderly residents, including assistance with medication administration and meal preparation.

A second key difference between nursing homes and assisted living facilities is their primary source of revenue. Under the Medicaid program, nursing home care is a covered service for those seniors poor enough to qualify. In Massachusetts, Medicaid pays for approximately 70% of nursing home patient care days. Unlike nursing home care, assisted living is generally not paid for under any public program.⁶ According to a 1997 survey by the Massachusetts Assisted Living Facilities Association, close to 64% of the residents pay for assisted living using only their own assets and income; another 16% have financial support from their family; the remaining 20% did not provide information. Many elderly supplement the services of assisted living with home health services, increasing their costs but also postponing or, in some cases, permanently averting admittance to a nursing home. The cost of assisted living varies, ranging from \$1,900 to \$5,000 a month, with the average one bedroom apartment (with services) costing \$3,200 per month.⁷ Nursing homes in Massachusetts charge approximately \$6700 per month to private paying residents.⁸ The higher cost of nursing home care is due to the higher level of care, primarily skilled nursing supervision, provided.

An important question that has yet to be answered is: what will happen to the healthier, wealthier and younger senior population in assisted living as it ages further? Will some residents eventually enter nursing homes continuing to pay out of pocket or after spending down to Medicaid eligibility? Alternatively, will some residents privately purchase ever increasing levels of care with assisted living facilities gradually becoming de facto nursing homes?

Nursing Homes Are Treating a Different Mix of Patients

The emergence of assisted living facilities is just one factor that has changed the population of nursing homes. Another trend is the sharp increase in end of life care now provided by nursing homes. Some patients have lived in nursing homes for years and die there foregoing hospital services; others are admitted near death from hospitals when acute interventions are discontinued. In

Site of Death, Massachusetts Residents

	1992	1999
Hospital	57.9%	45.9%
Nursing Home	19.2%	30.2%

seven years, the site of death for Massachusetts residents has shown a dramatic shift away from hospitals to nursing homes, with other sites (home, hospice, out of state) remaining relatively constant.

Another key change for nursing homes is the increase in the number of short-term patients admitted from hospitals for rehabilitation services. Medi-

care pays for up to 100 days of rehabilitation following an acute hospital discharge. While rehabilitation patients are generally younger and less chronically ill than long-term nursing home patients, they are being transferred after shorter hospital stays than ever before⁹ and they are coming for more intensive, expensive services such as physical and occupational therapy.

These changes in payer and patient mix have expanded the role of nursing homes beyond their traditional role of serving the chronically ill. Reduced demand overall for nursing home services, their increasingly high-demand patient mix, and the migration of their private paying clientele have all contributed to the current poor financial health of the nursing home industry. Further, the growing cost of nursing home care to state Medicaid budgets and the aging of the baby boomers have all brought greater urgency to creating viable private financing mechanisms for long-term care.

Options for Future Financing of Long-Term Care

There are some solutions for private long-term care financing, however, greater use of any of these mechanisms would require a significant change in public attitude and perception. Most individuals do not perceive that they need long-term care coverage, mistakenly thinking that the Medicare program will cover those needs. Instead, those who do not prepare often end up spending down their assets to become eligible for public assistance through Medicaid. If private solutions are to become a key part of the financing picture for long-term care, then individuals must plan for and assume greater responsibility for their future long-term care needs during their working years.

Three financing mechanisms for long-term care include long-term care insurance (LTCI), certain life insurance products, and viatical settlements. While none of these mechanisms will help the nursing home industry regain the less frail private paying patients lost to assisted living, they would likely benefit the industry by lessening its reliance on tax-funded government programs. Greater use of private funding will help state Medicaid budgets, since Medicaid funds most long-term care today. Individuals who plan ahead and use one of these financing mechanisms would also benefit since they may preclude or at least reduce the need to spend down assets to qualify for Medicaid.

Currently, less than 1% of all employers with 10 or more employees sponsor LTCI nationally¹⁰ and virtually none subsidize the cost as they widely do for health insurance. However, the federal government has taken the innovative step of sponsoring LTCI for its employees, expected to begin in October of 2002. This will create the largest employer-sponsored LTCI offering in the country.

With limited employer sponsorship of LTCI, the burden rests with individuals to purchase policies. The cost of such policies varies widely depending on the benefits chosen and the age of the purchaser. If purchased at age 55, an LTCI policy may cost less than \$1000 per year; by age 75, the policy could cost up to \$6,000 per year.¹¹ Experts also say that greater acceptance of this insurance at least partially hinges upon benefits being usable across various long-term care settings, a feature which is not always available in such policies currently. Despite these obstacles, the number of persons covered by long-term care insurance nationwide grew by approximately 140% between 1992 and 1998, from 1.7 million to 4.1 million.¹²

However, if one does not use one's long-term care insurance benefits, the money spent on the policy is gone. Some life insurance policies contain provisions that address this drawback. These policies have an accelerated death benefit that under certain circumstances allows the insured to receive monies from the policy that can be used to finance long-term care. Whether paid in a lump sum or in periodic installments, each payment received reduces the death benefit payable to the insured's beneficiaries. The rules and costs of such riders vary widely.

Viatical settlements gained prominence as a means for AIDS patients to finance their end of life care. It is an arrangement whereby a third party, usually a broker, purchases ownership of a life insurance contract covering a terminally ill insured. The percentage paid (usually 50-80% of the death

benefit) is inversely related to the insured's life expectancy. The disadvantage of a viatical settlement is that the benefits are time limited and leave the beneficiary without a survivor payment.

These private financing products require investment, planning, and consumer research to find the right match for the individual circumstance. Unlike employer-based health insurance, consumers are without an intermediary to sift through competing products. The wide array of choices between these alternatives and within the policies themselves presents a confusing challenge to potential consumers.

Conclusion

Over the last decade, there have been dramatic changes in the delivery of long-term care. But the biggest challenge is looming on the horizon. By 2025, the over age 85 population in Massachusetts is projected to grow by nearly 40% from 114,000 to 158,000. Access to a wide array of quality long-term care services and a viable funding mechanism will become a priority for this segment of the populace long before then. Innovative solutions involving both public and private sectors must be considered and developed now, to ensure quality, affordable long-term care for tomorrow's seniors.

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Did you know?

Higher Volume Lowers Risk

The Leapfrog Group, a consortium of major US health care purchasers, is in the forefront of a number of initiatives aimed at optimizing medical outcomes. One of their efforts draws upon several studies showing that for the five high risk surgical procedures listed below, significantly better clinical outcomes are associated with hospitals that perform more than a threshold number each year. While hospital data show that most people undergoing these procedures in Massachusetts are having them done in high volume hospitals, this is not the case for everyone. The table below shows what percentage of these procedures performed in Massachusetts in FY99 took place in a high volume hospital.

Procedure	Threshold Volume Recommended	Percent Performed in Mass. Hospitals that Meet Threshold
Coronary Artery Bypass Graft	500 or more per year	80%
Coronary Angioplasty	400 or more per year	99%
Carotid Endarterectomy	100 or more per year	43%
Abdominal Aortic Aneurysm Repair	30 or more per year	75%
Esophageal Cancer Surgery	7 or more per year	62%

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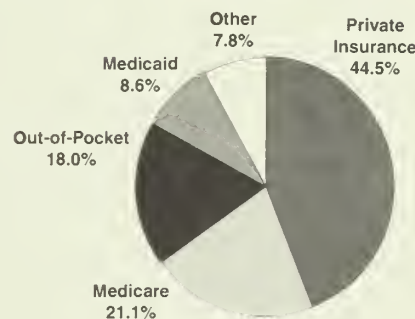
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OUT-OF-POCKET SPENDING FOR HEALTH CARE SERVICES

Although insurance covers much of the cost of medical care in the United States, most insured individuals and families also pay

out-of-pocket for some portion of their medical bills. Nationally, out-of-pocket spending accounts for almost one in every five dollars spent on health care, an amount nearly equal to national Medicare spending.¹ Despite the magnitude of consumer spending on health care, there is relatively little data about these expenses and how they are distributed across the population. While acknowledging that out-of-pocket expenses are certainly a greater burden for the uninsured, this issue of *Healthpoint* focuses on health care spending by the insured, policy concerns regarding these expenses, and the ways in which health care expenses are treated under tax law.

Health Care Expenses by
Payment Source, 1996



Understanding the Current Health Care Payment Climate

In an employer-based health insurance system, the portion of cost borne by employees in the form of out-of-pocket spending functions partly as a protection against "moral hazard," the tendency of the insured to use more health care services than they would if they paid the full cost of these services. Individuals who do not pay at the point of service for much of the cost of treatment tend to access care more often, at a lower level of need, or seek treatment that is more sophisticated or of a higher intensity than clinically indicated.² At the same time, there is little incentive for providers to compete on cost or be price sensitive in services such as inpatient care, for which insurance pays such a large part. In effect, payment by a third party weakens the incentive of both consumer and provider to be cost-conscious.

The growth of managed care has actually led to a decrease in the proportion of out-of-pocket costs paid by consumers for essential health services at a time when an aging population, the internet and direct to consumer advertising have increased health care spending overall. This is largely because managed care plans provide more comprehensive coverage of preventive care and prescription drugs, and employ less costly copay-

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Number 23 November 2001

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ments rather than more costly coinsurance. At the same time, our concept of health insurance has evolved from financial protection against the cost of treating disease or accidental injury to the expectation of first dollar coverage.³ A generation ago, middle class families budgeted for routine medical and dental spending, when health insurance was protection only from the expense of catastrophic illness and subsequent bankruptcy.

Policy Considerations

With Massachusetts employers facing a third year of substantial premium increases, some of which undoubtedly will be passed on to employees, one must ask how much an individual or family is capable of paying for health care and in what form are those charges easiest to absorb? At what level of contribution do individuals choose to access treatment too infrequently, too late, or forego a needed treatment or drug due to its cost? Employers and state health policy makers must consider whether out-of-pocket expenses fall equitably, if not equally, on all segments of the insured population, how best to use out-of-pocket fees to motivate patients to make cost-effective treatment choices, and what capacity employees have to pay out-of-pocket expenses.

How much of an insured individual's health care bill should be paid out-of-pocket relative to other sources of payment? This is a particularly salient question for Massachusetts, with its high managed care penetration rate, above national average use of teaching hospitals, higher than average per capita income, and employers who subsidize family health insurance premiums at a higher rate than the national average.⁴

Types of Employee Out-of-Pocket Expenses

Cost sharing of health expenses comes in several forms which differ in whom they affect, the ease in budgeting for them, their impact on seeking care, and their tax treatment. Insurance plans (whether managed or indemnity) and employers use some or all of the following forms of cost sharing to partially defray the cost of health services:

copayment—a specific dollar amount that doesn't vary with the cost of service. Copayments generally are set low enough not to deter appropriate care seeking, but may influence the site or type of care such as encouraging use of in-network providers or generic rather than brand name drugs.

reasonable and customary charge—the amount insurers assign to a health care service, often lower than what the provider actually charges.

balance billing—when providers bill patients the difference between their charge and the reasonable and customary amount paid by the insurer.

coinsurance—a percentage of the charge for health care services. When the reasonable and customary amount used by the insurer to calculate its share of the bill is lower than what the provider charges, patients effectively pay a higher coinsurance rate than the one stated (typically 20%) in their insurance policy.

deductible—a specific amount, usually \$100-\$1000 per family member, paid each year before insurance will cover services. Patients effectively pay more than the specified deductible when the

insurer tallies deductibles using the assigned reasonable and customary rate rather than the provider's charge. Insurers also may calculate physical and mental health service deductibles separately.

interior cap—the maximum amount covered by insurance per service or incident. Patients pay 100% of the amount exceeding the cap.

payment for services not covered by insurance—patients pay 100% of the charge for services not covered. Such services range from cosmetic to experimental procedures, alternative therapies, politically controversial services such as abortion, and those not considered medically necessary such as sterilization reversal, circumcision and, until mandated, breast reconstruction after mastectomy.

payment for covered services that a consumer chooses to pay out-of-pocket—usually for confidentiality or because a chosen provider does not participate in a particular plan, these services range from HIV and genetic testing to mental health services, as well as gynecological services sought by insured teenagers who prefer to pay out-of-pocket rather than involve their parents.

Another form of cost sharing, though not considered an out-of-pocket expense, is the employee contribution to the premium. While the amount of the employee contribution certainly affects the company's take-up rate (the percent of employees who accept offered insurance), it is not paid at the point of service and is not intended to affect the actual use of health care services. Employees may consider premium cost when they decide whether to accept insurance, however, in two surveys of Massachusetts residents, fewer than 30% of respondents who access health insurance through their employer, could recollect their monthly or yearly dollar contribution to the premium.⁵

Tax Treatment of Health Expenses—An Uneven Playing Field

The federal government, through its tax code, either attenuates or exacerbates the bite of health care expenses to employers and individuals. By making the employer portion of the premium cost tax deductible, the federal government foregoes revenue on presumably what would otherwise be a portion of the employee's income. This encourages rich benefit packages and penalizes those who obtain health insurance in the individual or non-group market since those premiums are not fully tax deductible in most cases. The employee share of the premium is consistently deducted from each paycheck, making this amount free from temptation, easier to budget and, therefore, among the forms of cost-sharing more easily absorbed. Employee premium contributions are increasingly deducted on a pre-tax basis, allowing those who earn enough to pay the required amount to lower their reportable gross taxable income.

Since 1978, the federal government also has allowed a pre-tax mechanism to pay for anticipated out-of-pocket medical and related expenses. Under the rules of these flexible spending accounts (FSAs), at the outset of a year, employees predict the amount they expect to pay out-of-pocket in uncovered or cost sharing expenses. The employer then deducts money on a pre-tax basis from each paycheck to cover those expenses, and upon submission of proof that the expense was incurred, reimburses the employee that amount from his account. The risk to the employee is that any unspent money is forfeited at the end of the year, so employees tend to estimate their expenses conservatively. However, these accounts do serve those in higher than average income groups by cushioning the impact of out-of-pocket expenses, especially those planned, but sometimes less medically neces-

sary services such as LASIK eye surgery, cosmetic surgery and orthodontia. While there is no statutory limit on the amount allowed in an FSA, most employers limit set asides to \$2000-\$3000 yearly.

Related to and often confused with FSAs, Archer medical savings accounts (MSAs) are currently available, but only to small businesses and the self-employed. To be eligible, one must have a high deductible insurance plan which also caps total allowable out-of-pocket expenses. One sets up a tax deferred savings account to pay for health care and health insurance expenses and is allowed to accumulate savings to pay for future medical expenses. One need not accurately estimate yearly out-of-pocket expenses nor forfeit unclaimed monies at the end of the year, however, the allowable contribution to the MSA depends on the size of the deductible.

For those with extraordinary out-of-pocket medical expenses, the federal government allows itemized deductions once those expenses exceed 7.5% of adjusted gross income, provided that they were not paid through an FSA nor an MSA. Only about 4% of the population in Massachusetts and nationally takes advantage of this deduction in a given year.⁶ Those who utilize the deduction tend to be in the middle to low income brackets since those with higher income are usually better insured and would need to spend quite a bit more out-of-pocket to exceed 7.5% of their income.

The next issue of Healthpoint will discuss health care services not typically covered by insurance, population groups who use such services disproportionately, and utilization trends for uncovered services showing that more consumers are paying out-of-pocket for the elective services they desire.

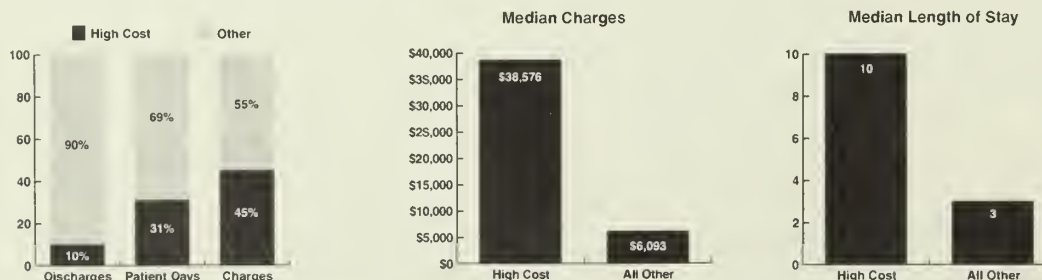
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Did you know?

High Cost Patients Use More Hospital Resources

Inpatient stays with charges of \$25,000 or more accounted for only 10% of discharges but 31% of patient days and 45% of charges in Massachusetts hospitals in FY00. After hospital discharge, 53% of these high cost patients needed non-acute care compared to just 27% of lower cost patients. Seven percent of high cost patients died in the hospital compared to just 2% of all other patients. The top three diagnoses for high cost discharges were major joint and limb procedures of the lower extremities, psychoses, and respiratory system diagnosis with ventilator support. Interestingly, psychoses was also one of the three most common diagnoses among lower cost discharges. The other two were birth related.



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CAN SOME AFFORD TO PAY MORE FOR COVERED HEALTH SERVICES?

All insured people pay out-of-pocket expenses for health care, but the nature, extent and burden of these expenses

vary significantly. A recent study found that substantial medical bills contributed to more than half of the nation's personal bankruptcies in 1999, even though the majority of those individuals had some type of health insurance.¹ On the other hand, the American Society of Plastic Surgeons reported a 198% increase from 1992 to 2000 in the number of cosmetic surgeries—elective surgeries not covered by insurance.²

While the popular perception is that out-of-pocket spending for health care greatly increased in recent years, careful analysis shows that this is not so, even when elective spending is included. This *Healthpoint* examines trends in elective health expenditures, and provides evidence that some people have the capacity to assume greater responsibility for the cost of the covered medical services they use.

Increase in Health Care Costs Modest for Most

An article in *Heath Affairs*³ analyzing Consumer Expenditure Survey (CES)⁴ data, concluded that for those with employer based insurance, total out-of-pocket spending (employee contribution to premium, copays, deductibles and payments for uncovered services) increased only 4.2% from 1990 to 1997 (see table). A 23% decrease in out-of-pocket spending (primarily in medical care) largely offset a 29% rise in the employee contribution to premium. Since many employers deduct the employee contribution on a pre-tax basis while copays and deductibles are paid after taxes, this trade-off generally benefited tax-paying employees.

Consumer Expenditure Survey 1990, 1997

	1990	1997	% change
Total Direct Expense	\$512	\$396	-23%
Medical	\$360	\$260	-28%
Drugs	\$140	\$128	-9%
Premium Expense	\$532	\$684	29%
Total Expense	\$1,040	\$1,084	4.2%

The transition to managed care in the 1990s played a large role in reducing out-of-pocket non-premium spending. Use of copays rather than coinsurance, and coverage of preventive care (both hallmarks of managed care) contributed to this reduction. In 1997, households in HMO/POS plans spent 5% less on premium contributions than those in indemnity plans, but even more significantly, spent 41% less on out-of-pocket medical and drug expenses (\$304 versus \$512).

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From 1990 to 1997, households earning over \$50,000 annually enjoyed a 38% reduction in medical and drug spending (see table), that contributed to a net reduction of 4% in their health care expenses. This is directly attributable to the shift from indemnity insurance to managed care.

**Out-of-Pocket Spending Trends
by Income 1990, 1997**

	1990	1997	% Change
Medical and Drug Expenses			
Higher Income	\$732	\$452	-38%
Lower Income	\$424	\$392	-8%
Premium Expense			
Higher Income	\$600	\$832	39%
Lower Income	\$508	\$676	33%
Total Expenses			
Higher Income	\$1,332	\$1,284	-4%
Lower Income	\$932	\$1,072	15%

While most Americans experienced this shift, higher income families benefited most because of their spending patterns under indemnity insurance. Higher income households, better able to afford out-of-pocket expenses, were probably more likely to have obtained preventive services not covered by indemnity insurance, and to have used doctors who charged higher than average fees. Since managed care plans cover preventive services and prohibit balance bill-

ing, out-of-pocket spending was reduced more for high income households than all others because they no longer paid out-of-pocket for these expenses.

In contrast, households earning \$20,000 to \$50,000 spent a substantial 15% more in 1997 on premiums and medical expenses than in 1990. Therefore, while Americans with employer based health insurance spent only 4.2% more for health care in 1997 than in 1990, lower income families' expenses increased more than three times that amount.

Some Consumers Elect to Spend More

While most insurers increased premiums sharply after 1997, a strong national economy lasted through early 2001 that helped consumers afford not only their rising contribution to premium, but also a variety of elective health services. Three categories of services (alternative therapies, cosmetic surgery, and refractive eye surgery) fall outside the coverage of all but the most generous plans, and yet thrived despite consumers footing the bills entirely out-of-pocket.

Alternative Therapies—So-called alternative therapies are a variety of services originally associated with non-Western medicine whose appeal has since spread broadly. A survey estimated that in 1997 Americans spent \$12.2 billion out-of-pocket on visits to alternative therapists and an additional \$14.8 billion on herbal remedies and other products related to alternative therapies. This \$27 billion is comparable to the estimated out-of-pocket expenses for all US physicians' services in 1997.⁵

Cosmetic Procedures—The aging of the baby boom generation and a strong economy fueled an upsurge in consumer spending for cosmetic procedures. In 2000, more than 1.3 million people (triple the number in 1992) had procedures performed by board-certified plastic surgeons. The most popular procedures were liposuction, breast augmentation (despite well publicized litigation over leaking silicone), eyelid surgery, and face-lift. Twenty-three percent were repeat patients and 38% had more than one procedure at the same time. Surgeon charges ranged from \$3,000 for upper and lower eyelid surgery to \$5,000 for a face-lift, for a total of \$7.5 billion spent out-of-pocket by consumers in 2000, not including hospital charges.⁶

Refractive Surgery—Eye surgery such as radial keratotomy and LASIK corrects visual acuity with the objective of reducing or eliminating the need for glasses and contact lenses. In 1999, there was

a 98% increase in these procedures from the previous year, down slightly from a 104% increase in 1998. In 2000, consumers spent almost \$2.5 billion out-of-pocket on refractive surgeries.⁷

The Market for Non-Covered Services

Medical services not covered by health insurance follow a for profit business model. Like any other luxury good, these services compete for discretionary income and usage varies with the strength of the economy. As noted in *Refractive Market Perspectives*, "costly zero interest financing plans initiated by leading auto makers may be shifting limited discretionary spending towards new car purchasers [and away from LASIK surgery]." In fact, in large part due to the slowing economy, the number of Americans undergoing elective vision surgery decreased in the second and third quarters of 2001 compared with the first quarter of 2001.

Practitioners who rely primarily on the self-pay market and provide an expensive service such as orthodontia, cosmetic or refractive surgery, routinely offer payment plans, free consultation and accept credit cards. Some practitioners also advertise directly to consumers; again, according to *Refractive Market Perspectives*, "Consumer demand [for laser surgery] was fueled by record spending on patient marketing including the industry-wide average spending of \$200 per procedure on direct marketing."

As providers felt the pinch of reduced revenue from insurers, some diversified their businesses to incorporate a high-end, self-pay market, along with or replacing their traditional lines of business. Examples include the widespread introduction of cosmetic teeth whitening by dentists and tattoo removal by laser surgeons. At the institutional level, well known hospitals from the Mayo Clinic to Massachusetts General Hospital routinely solicit and treat wealthy self-pay patients from other parts of the US and abroad.

The newest luxury offering for the high-end, self-pay market is the high profile medical practice about to be opened by two former Beth Israel physicians. For \$4,000 a year, in addition to the insurer reimbursement for individual visits, this practice will provide 24 hour access and highly individualized service to a small group of patients. Other practices have ceased to contract with insurers of any type. While restricting a medical practice to private self-pay patients has been called "a return to old fashioned medicine," it is the more personalized service that is old fashioned, not its cost.

Lack of Consistent Data Hinders Policy Making

Given the huge amount of money consumers spend out-of-pocket for health care services, too little is known about these expenditures. The CES does not offer enough detail on spending by income level nor does it differentiate between spending on services that are medically necessary and those that are elective. Moreover, consumers themselves have very short memories about their expenses, with barely a third of them able to recall for a surveyor even their family's steady contribution to their insurance premium.⁹

This lack of adequate data makes it difficult to assess people's capacity to pay more of the cost of their covered care, as they surely will be asked to do if costs continue to rise. It seems clear from the \$37 billion spent on just three elective services that some people do have the ability, if not the willingness, to pay more for the covered services they use. Many experts contend that ever rising health care costs nationally are due in part to the insulation most Americans have had from the cost of the choices they make for these services. If they become more financially engaged, it could have the salutary effect of causing a slow down in the rise of health care costs.

The Role of Employers

In most companies, the range of earnings is quite diverse, yet employers tend to subsidize premiums equally or sometimes even more generously for their highest paid employees. By contrast, Harvard University uses an innovative strategy that most heavily subsidizes the premiums of employees earning \$55,000 or less annually with the explicit aim of increasing the take-up rate of its lowest paid workers. Employers striving to continue offering health insurance despite rising premiums, would do well to introduce out-of-pocket policies that influence consumer behavior rather than just share cost. Employers must seek a balance in strategy that will not deter low income workers from accepting health insurance and accessing needed care, while encouraging higher income workers to assume more responsibility for the health care choices they make.

For more information on health care spending by the insured, types of employee out-of-pocket expenses, and their treatment under tax law, please see the previous issue of Healthpoint, "Out-of-Pocket Spending for Health Care Services."

Endnotes

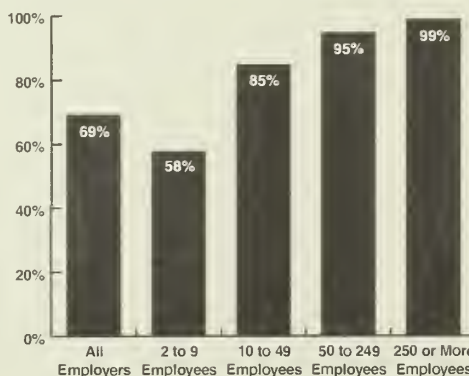
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Did you know?

More Massachusetts Employers Offer Health Insurance

In a recent survey of 1,100 Massachusetts employers, the Division of Health Care Finance and Policy found that 69% of all private sector establishments offer health insurance to their employees. This is considerably higher than the national offer rate of 59% found by the US Medical Expenditure Panel Survey in 1999. A high rate of employer offered insurance is correlated to at least two factors characteristic of Massachusetts: high per capita income and a high proportion of large employers. Per capita income in 2000 was \$37,710 in Massachusetts compared to \$29,451 nationally. In addition, Massachusetts has a greater proportion of employers in every size category above 20 employees than does the nation as a whole. For additional results from the employer survey, please visit www.mass.gov/hrsa.

Percent of Private Sector Establishments Offering Health Insurance, by Size (2001)



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Massachusetts is an international
ally recognized leader in medical
care, but dental care does not

DENTISTRY NEEDS MORE ATTENTION BUT SHOULD NOT FOLLOW MEDICINE

share the limelight. Although largely preventable, dental decay is the most common chronic condition of childhood, affecting 84% of all children nationally by age 17.¹ While newspapers throughout the Commonwealth are filled with articles about health care, these stories are about medicine, not dentistry. Even the appropriation of the term "health insurance" to mean medical, but not dental, insurance is telling evidence that dental care generally takes a backseat to medical care.

Although they share many characteristics, dentistry and medicine have diverged in significant ways, particularly over the last twenty years. While medicine appears to have trumped dentistry in visibility and importance, it is a profession in turmoil. Physicians are unhappy with their lost autonomy, interrupted relationships with long time patients, and severe pressure over productivity. Generally, dentists have not experienced these types of professional losses; their challenge is to work for the recognition of oral health as a vital part of overall health status while avoiding some of the unfortunate circumstances now faced by physicians. This issue of *Healthpoint* examines the structure of the dental care system particularly in contrast to our medical system and describes some ramifications of oral health's second class status.

Delivery Structure

The dental industry today looks remarkably like the medical industry of the early 1980s. Steep increases in medical insurance premiums facilitated the swift incursion of managed care into medicine, propelling physicians into larger and larger groups for perceived economies of scale, to amass capital for computer systems, and to bulk up for negotiating with HMOs. In addition, and quite significantly, many hospitals purchased medical practices to ensure the flow of patient referrals, causing many physicians to transition from self-employment to employee status for the first time. This has not occurred in dentistry. Almost all dentists are still in private practice, mainly solo, paid either by private fee-for-service (indemnity) dental insurance or out-of-pocket by their patients.

Dentistry is efficient in that it relies heavily on cost-effective general practitioners who, in turn, rely heavily for preventive care on very cost-effective dental hygienists. While dental hygienists and dental assistants are less broadly and deeply trained (par-

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ticularly in treatment) than nurses and physician assistants, they have been more successful in carving an independent role for themselves and are a moderating influence on the cost of dental care.

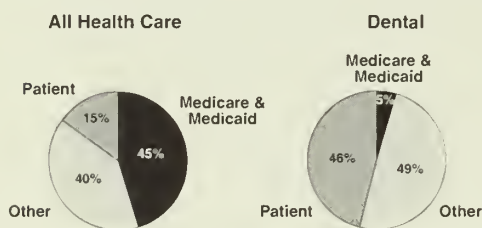
Coverage

As early as 1957, the American Dental Association endorsed prepaid dental care while for years the American Medical Association adamantly opposed prepaid medical insurance, regarding it as socialized medicine. Yet in 2000, more than a third (35.4%) of Massachusetts adults ages 18 and older reported that they lacked dental insurance² compared with only 7% who reported that they lacked medical insurance.³ In that same year, Massachusetts ranked among the top ten states for enrollment in prepaid dental plans,⁴ even though just 51% of Massachusetts workplaces reported offering dental insurance when surveyed in 2001.⁵ Nationally, premiums for individual dental coverage averaged \$12-\$25 monthly in 2000,⁶ while the 2001 average monthly medical insurance premium in Massachusetts was \$295 for individual coverage.⁷ Despite the significantly higher cost, 69% of Massachusetts establishments offer medical insurance.⁸

Out-of-Pocket Spending

The percent of Massachusetts adults reporting a dental visit (77%) is higher than the 65% reporting dental insurance (and similar to the 80% reporting a routine medical checkup), so it appears that at least some people are willing and able to pay out-of-pocket for dental visits.⁹ The Centers for

Payer Mix: All Health Care versus Dental (1999)



Medicare and Medicaid Services (formerly HCFA) estimated that nationally, patients paid out-of-pocket for 46% of dental expenditures, but for only 15% of total health care expenditures (including dental) in 1999.¹⁰ In contrast to medicine, the relative scarcity of dental insurance and the absence of managed care in existing dental plans means that those people who seek care have always had to assume at least some responsibility for their dental bills.

This has contributed to dentistry's relatively stable prices and, many would argue, has promoted the responsible use of dental services which employers and policy makers are now trying to re-emphasize in medicine.

One reason many patients pay for dental care out-of-pocket is that they can. Managed care in medicine owes its broad acceptance in large part to skyrocketing premium increases stemming from rapid pharmaceutical and technological advances. Dental prices have been relatively flat and more affordable because dentistry has not been similarly transformed. In addition, dentistry is characterized by relatively infrequent need for acute care service, so a routine check-up is often the only item for which one needs to budget.

Public Assistance Programs

Reflective of dentistry's fragmented coverage by public programs, in 1999 Medicare and Medicaid covered only 5% of dental expenditures nationally, but 45% of all health care expenditures.¹¹ The federal government sends an unfortunate message to the general public about the importance of oral health by deeming the coverage of adult dental services "optional" for state Medicaid programs while requiring coverage for children. In Massachusetts, MassHealth had long included adults in their dental coverage but recently succumbed to extreme budgetary pressure and joined 35 other

states in reducing that coverage for most adults, except for special circumstances. The reduction of most adult dental services within MassHealth is bound to increase existing economic disparities in oral disease and survival rates for oral cancer, and underscores the second class role of dentistry within the world of health care.

Over the past two years, the Commonwealth provided approximately \$6 million to community health centers (CHCs) and other community organizations to increase their capacity to deliver dental services to MassHealth members and other low income individuals. This year Massachusetts designated approximately \$2 million more to meet even greater anticipated demand. The Uncompensated Care Pool (the state's health care safety net for the uninsured), pays for both preventive and acute dental services at CHCs. In addition, low-cost dental care is available at the Commonwealth's three schools of dental medicine and six schools that train dental hygienists.

Seniors in traditional fee-for-service Medicare are not covered for dental services, but those enrolled in Massachusetts Medicare HMOs have limited dental coverage. The lack of dental coverage by Medicare means that dental care for seniors is problematic. Among Massachusetts seniors in 2000, 60% of those ages 65-74 and 72% of those 75 or older had no dental coverage.¹² A 1999 report stated that 22% of elderly residents had no teeth at all.¹³

Nationally, children lose about 632,000 school days due to oral health problems.¹⁴ Among Massachusetts children ages 3-17, nine percent needed dental care in 2000 but could not get it because of the cost.¹⁵ According to community surveys, dental sealants, among the most cost effective of preventive dental services, have been applied to fewer than 25% of Massachusetts schoolchildren despite strong endorsement by the dental community and federal government. School mouth rinse programs in non-fluoridated communities are rare in Massachusetts even though fluoride mouth rinse has been shown to reduce tooth decay up to 35%.¹⁶

Which Delivery Structure Supports Uncompensated Care?

Policy makers disagree on the structural factors that facilitate offering free care. One theory is that two by-products of managed care (the emergence of larger provider groups pooling overhead, and large enough patient bases to allow revenues from well insured patients to offset the cost) would encourage more providers to offer free care. Others theorize the opposite: that a recent national decline in the amount of free care physicians provide was due to a decrease in solo or small group practices, a decrease in physicians owning their own practices, and an increase in managed care.¹⁷ The former theory would seem to argue that solo practice dentists would find it difficult to offer free care while the latter theory seems to suggest that dentistry's practice structure would facilitate offering free care. But one significant difference between the two professions confounds the situation: the far greater proportion of self pay patients in dentistry, always acutely price sensitive, discourages the cost shifting essential to financing free care.

What Can Massachusetts Do?

In 1998, for only the third time in fifty years, the Massachusetts legislature called for an assessment of oral health status that called attention to a "collapsing" dental delivery system, particularly for low income residents, and urged the state "to play a leadership role in population-based dental disease prevention and surveillance." It pointed out that although Massachusetts has been in the forefront of public health since the 19th century, 43% of our population live in communities with non-fluoridated water supplies, making the Commonwealth 35th in the nation for this basic public health

measure.¹⁸ A 1998 article by the Massachusetts Dental Society stated unequivocally that "...fluoridation [having been shown to reduce tooth decay by up to 40%] is still the most cost-effective preventive measure for dental disease and needs to be promoted once again in Massachusetts."¹⁹

Massachusetts also needs to better integrate oral health care into overall health care delivery and the public health infrastructure so it is readily available to everyone. The safety net for low-income adults and seniors must be strengthened and secured particularly because there is likely to be greater demand on it. An important step taking place this spring is fee enhancement by MassHealth for pediatric dental services that should encourage providers to join the program.

Other improvements to our oral health system would include legislative expansion of the number of communities with fluoridated water supplies, increased funding for programs administered by DPH's Office of Oral Health and School Health Unit, and promoting the use of mouth guards by all during contact sports. Finally, more complete integration of dental care data into our public health and medical care databases is crucial to measure our progress moving forward.

Endnotes

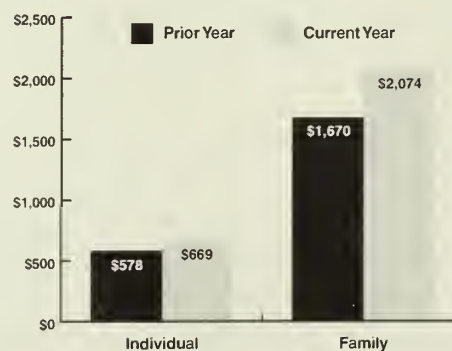
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Did you know?

Employers Decreased Contributions to Family Plans

In a recent survey of 1,100 Massachusetts employers, the Division of Health Care Finance and Policy found that from 2000 to 2001, health insurance premiums for an employer's most popular (or only) health plan rose an average of 19% for individual coverage and 15% for family coverage. But while employers kept their contribution to individual health insurance plans steady at 81% of the cost, they decreased their contribution to family coverage from 75% to 73%, on average. The overall premium increase, coupled with the 2% employer rollback in subsidy to family coverage, resulted in an average net increase of 24% (from \$1,670 to \$2,074 annually) to what employees contribute to their family plans. At the same time, employees with individual plans saw their average contribution to the premium rise 16% (from \$578 to \$669 annually).

Average Annual Employee Contribution to their Medical Insurance Premium (2001)



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CLINICAL TRIALS: PROMISE AND PROFIT

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are the final step in a long, complex, and often costly process of testing potentially promising drugs or medical devices. Required by the Food and Drug Administration (FDA) before a drug or device is approved for general use, the clinical trial process was designed to provide impartial scientific evidence of effectiveness and safety. Only approximately 20% of the drugs that start the process eventually meet the FDA's approval criteria. The National Institutes of Health's clinical trials budget for FY03 is estimated to be \$2.8 billion, a 31% increase from FY01,¹ and a sum that is dwarfed by spending on trials by private pharmaceutical companies. Underscoring the increasing importance of clinical research is a new state law, effective January 1, 2003, requiring Massachusetts insurers to cover patient care costs associated with cancer treatment trials. This issue of *Healthpoint* examines the burgeoning clinical trials industry and looks at how a prescription drug goes from formulation to pharmacy.

History

Federal regulation of drugs began in 1906 with passage of the Food and Drugs Act which required that drugs meet standards of strength and purity, but not necessarily effectiveness. Significant progress was made toward more comprehensive regulation in 1938 and 1962, when laws were enacted stipulating that stringent standards of safety and effectiveness be met before a prescription drug could be marketed or sold. The 1962 legislation, recognizing the advent of clinical trials, also made informed consent a prerequisite for patients participating in such trials and required that sponsors send adverse drug reaction reports to the FDA, thus increasing its consumer protection responsibility. This responsibility expanded in 1972 when the FDA began a formal review of all over-the-counter drugs. While the first recognized randomly assigned clinical trial took place in Great Britain in the 1940s to test streptomycin in tuberculosis patients, trials didn't proliferate until the 1970s. In 2002, there were approximately 80,000 trials nationwide.²

FDA Involvement, Institutional Review Boards, and Patient Protection

Once a new drug or treatment has been successfully tested in laboratories and in animals—it is estimated that only 5 in 5,000 compounds that enter pre-clinical testing advance to human testing³—its sponsor applies to the FDA for permission to begin test-

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Number 26 January 2003

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ing in humans. Both the FDA and a local institutional review board (IRB) must approve the trial protocol and informed consent procedures before a trial may begin. IRBs are located in hospitals and research institutions, and include physicians, scientists, non-scientists, and community members.

At present, the FDA, the federal Office for Human Research Protections, and IRBs are the three main components of patient protection. However, after the death of a participant during a clinical study of gene therapy in 1999, the U.S. Department of Health and Human Services directed the Institute of Medicine (IOM) to study and recommend ways to increase patient protection. In its recently released report, the IOM suggested establishing an independent, nonpartisan advisory body to shore up the strength of the protection system, and creating universal research standards to protect participants in both publicly and privately funded clinical studies.⁴

Description of Clinical Trials

Clinical trials test drugs, treatments or devices developed to prevent, detect, diagnose, screen for, or treat a disease, or to improve care and comfort for people with a disease or condition. Generally, there are four phases of a clinical trial. At least three phases must be completed before final FDA approval; if a fourth phase is conducted, it usually occurs after approval to explore new uses, long-term safety, and effectiveness. Phase I trials primarily determine safe dosage and how best to administer a drug while measuring its side effects; they typically last several months and include 20 to 100 people. In the case of cancer clinical trials, phase I trials generally involve patients with advanced disease who have not responded to standard treatment. About 70% of drugs tested in phase I progress to the next phase. Phase II trials involve 30 to 300 people and determine if a new drug or treatment produces the desired effect. In cancer treatment, participants are considered to have “responded” if their tumors shrink significantly or their disease progresses at a slower pace than expected. Phase III trials, which involve hundreds to thousands of people, can begin if a significant proportion of phase II patients “responded.” A new drug or drug combination is compared to standard therapy or a placebo by randomly assigning patients to a control group, which receives the standard therapy, or to a treatment group, which receives the new therapy. Often phase III studies are “blind” (patients do not know which treatment they are receiving) or “double-blind” (neither patients nor investigators know who got which treatment) until the data are analyzed.⁵

FDA Approval of New Drugs

After a clinical trial is completed, the sponsor submits a new drug application (NDA) to the FDA that includes the study results, the drug’s composition and how it behaves in the body, as well as how it will be manufactured and packaged. Due to external pressure from pharmaceutical companies and patients, the FDA has sped up its review of these data. The Prescription Drug User Fee Act of 1992 requires those seeking approval for a drug to pay a fee with their application, enabling the FDA to hire additional staff to review applications more quickly.

The FDA has streamlined the drug application review process by creating two categories for drugs being reviewed—standard and priority. Standard drugs (usually reviewed within a year) are expected to offer minor improvements over existing drugs. Priority drugs (usually reviewed within 6 months) represent potential major advances, so more FDA resources are provided throughout the review. The FDA also may choose to approve a drug through a process called “accelerated review,” designed for drugs that are expected to have significant benefits in the long-term.⁶ For example, trials of a cholesterol-lowering drug do not immediately show a reduction in deaths from heart disease,

but the drug does lower cholesterol, which other research shows is likely to eventually reduce deaths from heart disease. The FDA may require post-approval studies on a drug approved in this way.

Finally, beginning in the 1970s, the FDA permitted early use of promising, but not yet approved, investigational drugs for people with life-threatening or debilitating diseases. This shortcut was first used to treat people with beta blockers who suffered from heart and lung conditions, and later allowed the widespread expedited use of AZT for AIDS patients when its effectiveness was observed in a phase II trial.⁷ In such circumstances, the FDA still requires the collection and submission of data on how patients react to the investigational drug.

Patient Participation and Recruitment

For various reasons, only a small segment of the population (3-5% of adults with cancer, for example)⁸ participates in clinical research studies—relatively few patients meet trial criteria, some eligible patients are hesitant to enroll, and some doctors are reluctant to refer their patients. As researchers turn their attention from acute illnesses to increasingly prevalent chronic diseases, many more participants are needed for clinical trials since the effect of drugs typically takes longer to manifest in patients with these conditions. To expand trial enrollment and improve accessibility, academic medical centers (AMCs) are developing relationships with community hospitals and physician groups.

To better understand the various effects of new drugs on specific demographic groups, in 1988 the FDA began requiring drug sponsors to report clinical trial data by age, gender, and racial subgroup. A growing number of seniors are enrolling in trials as a result of the 2000 requirement that Medicare cover routine costs of care associated with trials. While both genders are well represented in trials, there is ongoing debate about the adequacy of racial minority representation. A recent study sponsored by the Agency for Healthcare Research and Quality documented a lack of racial and ethnic diversity among patients participating in HIV clinical trials. Especially under-represented were blacks and Hispanics, who comprise 48% of those with HIV in the United States.⁹

Insurance Coverage

Legislation requiring health plans to cover patient care costs associated with clinical trials is relatively new at the state level; as of December 2001, 15 states had such mandates. Massachusetts requires all fully insured (i.e., not self-funded) plans to cover the same patient care services (such as blood and urine tests) for enrollees in a qualified cancer treatment clinical trial that they would for patients not in a trial. Plans are not responsible for costs associated with managing the research, items provided by the trial sponsor (such as the drug itself), or the cost of services performed solely to meet the needs of the trial. Since many insurers have been covering such services for cancer patients, some assert that this mandate simply formalizes existing practice.

The Clinical Trial Industry

Clinical trials are now a distinct industry due to their growing number and the ancillary businesses that have emerged to facilitate them. While the overwhelming majority of studies in the past were administered by AMCs, many functions are now performed by private, for-profit companies devoted solely to the introduction of new drugs to the market. In 1998, only 40% of industry money was directed to AMCs, half of what was directed to them in 1990. Pharmaceutical companies now hire contract research organizations (CRO) for protocol design and trial administration, and employ their own physician-scientists, pharmacists, and statisticians to conduct the studies. In turn, CROs

develop relationships with a variety of physicians to gain access to their patients, though the pharmaceutical company retains control of the trial and the dissemination of results.

Allowing entities that have a financial stake in the results to control clinical trials eliminates the historic fire wall between those who evaluate new drugs and those who stand to profit if the tested drug is approved. Physicians increasingly report pressure, censorship, and the threat of fund cutoff by companies not wanting negative trial results published.¹⁰ In response, the International Committee of Medical Journal Editors in 2000 revised their author guidelines in an attempt to minimize the influence of private interests. However, the *New England Journal of Medicine* recently concluded that the guidelines are not being adhered to and called for re-examining the contracting process.¹¹

Policy Implications

The demand for rapid approval of drugs and devices, and the time needed to ensure safety and efficacy, remain a challenge for researchers, patients, and the FDA. The responsibilities of IRBs and the Office for Human Research Protections are increasing, yet resources remain limited. Inappropriate conduct arising from conflicts of interest must be more effectively guarded against to uphold the integrity of the clinical research process.

Endnotes

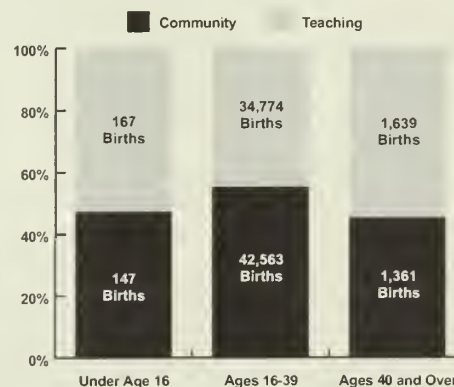
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Did you know?

The Youngest and Oldest Mothers Deliver at the Same Hospitals

Both community and teaching hospitals in Massachusetts offer maternity services. In FY01, 55% of the state's 80,651 births occurred in the 38 community hospitals with maternity units. Women ages 16-39 tend to use community hospitals while women younger than age 16 and older than age 39 are more likely to deliver in teaching hospitals. Women ages 16-39 gave birth to 96% of the infants born in Massachusetts in FY01. However, the fastest growing age group of maternity patients is "ages 40 and over," which has increased 46% since 1995. By contrast, births to those younger than age 16 have decreased 39% since then.

Distribution of Massachusetts Births by Age of Mother and Hospital Type (FY01)



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DIAGNOSTIC IMAGING: A NEW COST DRIVER

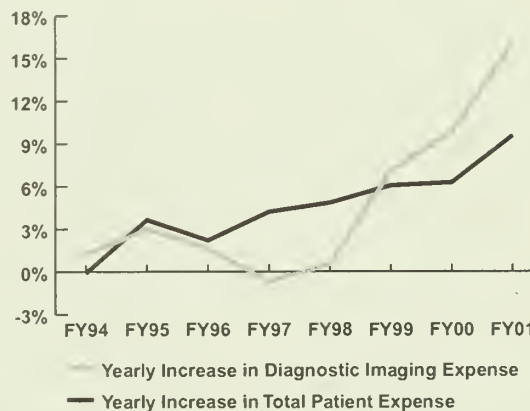
With steep increases in health care premiums

once again in the news, much attention is focused on the question of which components of the premium are driving the increases. Pharmacy costs, while still increasing, have begun to moderate. However, a new area of concern has emerged: diagnostic radiology services. From FY99 through FY01, the combined expenses of three different types of imaging services—diagnostic radiology, Computed Tomography (CT) scans, and nuclear medicine—exceeded the average rate of increase in overall expenses in Massachusetts hospitals, after at least five years of low growth (see figure).¹

Although the aging population may account for some of the increase in utilization, technological advances, the penetration of radiological services throughout medicine, patient demand, and other developments have had a greater effect.

This issue of *Healthpoint* focuses on the factors causing the rapid increase in the cost of diagnostic radiology, the clinical gains attributable to the growth in radiology services, and strategies that might be adopted to control this growth.

Rate of Increase in Diagnostic Imaging and Total Patient Expense, FY94-FY01



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Cost Drivers

In a recent national survey, physicians named magnetic resonance imaging (MRI) and CT scans as the two most important medical advances of the past 30 years.² Improved diagnostic capability though, often comes with a high price tag—as much as \$2.5 million for each MRI machine. At the same time, the development of relatively cheap imaging equipment that produces high-quality images has enabled the proliferation of this equipment into physician offices. Radiology procedures have become so widespread throughout medical practice that a recent analysis found that New England physicians in 38 different specialties had billed Medicare for the interpretation of radiology results.³

Number 27 April 2003

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Division of Health Care
Finance and Policy

This diffusion of technology into so many specialties has blurred the traditional distinction between the physician who orders radiology procedures and the radiologist who performs and interprets the results. X-ray equipment in orthopedic suites, ultrasound machinery in obstetrics offices, and cardiovascular imaging devices in cardiology practices all increase patient convenience, and eliminate the need for the radiologist "middleman," while providing an additional revenue stream for the treating physician. Physician self-referral, regulated by Medicare and Medicaid, but not by other insurers, has been shown to be associated with higher utilization rates.⁴

Not only has the use of diagnostic imaging diffused to many medical specialties, it has spread geographically to both community hospitals and local non-hospital imaging centers. Community hospitals acquire the newest radiology equipment to compete with tertiary hospitals in attracting physicians and patients. When patients must go to tertiary hospitals for diagnostic tests, community hospitals often lose them for the entire treatment cycle. Moreover, some diagnostic radiology services may be profitable, even when no therapeutic treatment is provided.

Other factors may also increase utilization. Direct-to-consumer advertising has touted whole-body scans as appropriate for healthy consumers despite controversy over the value of such scans. Technological advances increase the patient-friendliness of certain tests, such as "open" MRI machines that minimize claustrophobia and CT scanners that perform exams 8-16 times faster than older models. The availability of colonography, a virtual examination of the colon, is likely to motivate more adults to submit to colon cancer screening since the more invasive colonoscopy is widely disliked. Finally, physicians explain some overuse of diagnostic testing as defensive behavior resulting from their fear of malpractice suits.

While some payers and purchasers report that the number of diagnostic tests performed is rapidly increasing, the intensity of service may also be increasing as expensive CT and MRI scans become more commonplace. Expansion of insurance coverage for new technologies, such as Medicare coverage of PET (positron emission tomography) scans to monitor the progress of breast cancer patients, will inevitably boost the utilization of those procedures. On the other hand, non-invasive CT scans are replacing more costly and dangerous angiograms to diagnose clogged arteries, and three-dimensional imaging is giving surgeons a better idea of what to expect during surgery. In some cases, the detail revealed in higher-quality imaging may negate the need for surgery altogether. Furthermore, it is estimated that three-dimensional imaging costs 65%-75% less than invasive diagnostic procedures.⁵

Issues

There is no doubt that many advances in diagnostic imaging have been tremendously beneficial to patients. However, under- and over-utilization of various procedures among subgroups of the population have not spread the benefit uniformly or with maximum efficiency. Racial and ethnic disparities in cardiac testing were recently documented despite controlling for the severity of the patient's illness.⁶ In addition, some proven screening tests like mammography are not performed as widely or frequently as recommended (see table).⁷

Mammography Rate by Residency, 1999

	Screenings per 1,000 Female Medicare Enrollees, Ages 65 to 69
Boston	508.1
Springfield	477.1
Worcester	403.1
United States	436.4

Note: An annual or bi-annual mammography is recommended for all women ages 50 to 69 (500 tests annually per 1,000 in this age group).

Conversely, whole body scans on the "worried well," widely regarded as having minimal benefit, have the additional disadvantage of triggering expen-

sive and sometimes risky follow-up care due to false-positive findings in the scan. Insurers, even when they have not paid for the scan, usually pay for the follow-up care. One study reported this year found that nearly half of all body scans show one or more abnormalities, even though just one percent is likely to indicate a serious illness.⁸

Despite rapid growth in many types of radiology services, there exists considerable concern about the adequacy of current and future capacity to meet demand. Already at some Massachusetts hospitals, appointments must be made far in advance for screening services such as mammography and colonoscopy, primarily due to a shortage of qualified staff. While growth in the supply of radiologists has been somewhat more rapid than that in most other specialties over the past 25 years, it may be that demand for radiology procedures has grown even more rapidly. The Massachusetts Medical Society rates radiology among the top eight specialties currently experiencing high vacancy rates statewide. Hospitals report vacancy rates of 10% or more for technicians in radiology, radiation therapy, ultrasound, and nuclear medicine, although the 10% vacancy rate among nurses garners far more attention.⁹

Strategies

Payers and purchasers have implemented a number of strategies to bring pharmaceutical costs under control, some of which may be models for managing radiology usage. Diagnostic imaging, however, is different from pharmacy in that it is a service, not a commodity. Except for short periods when new services are introduced, there are typically many alternative providers of these services. There is no parallel to the single-source drug, so often the villain in discussions of pharmacy costs.

Theoretically, selective contracting by insurers for radiology services is possible, although practically, this may be suitable only for the more infrequent, expensive procedures in cases where a result is not needed immediately. Currently, most radiology services are too integral to the provision of care to remove them from their usual service location. However, the increasing availability of digital equipment to produce, transmit, and store radiological images will decouple where imaging services are provided, interpreted, and perhaps, also where treatment occurs, raising thorny questions of accountability, credentialing and quality assurance. Massachusetts General Hospital, for example, uses radiologists in Bangalore, India to interpret CT scans,¹⁰ and the Medical Center of Central Georgia transmits second and third shift CT scans to radiologists in Australia, eliminating the need for and expense of on call radiologists.¹¹

Payers and policy makers may want to consider carefully the concerns raised by physician self-referral. Both Medicare and Medicaid have self-referral restrictions pertinent to radiology services, although there are various exemptions. Some states have passed statutes that regulate physician self-referral of private-pay patients as well, although Massachusetts is not one of them.

Tiered copayments are another possibility, although their potential for limiting utilization in this area is unproven. To the extent that patients are requesting more expensive versions of diagnostic procedures than they may need, increased cost-sharing might serve as a deterrent. Patient education campaigns, such as those concerning the appropriate use of antibiotics, might also be effective in discouraging patients from seeking inappropriate body scans or other unnecessary tests.

A better strategy might be to employ practice guidelines to encourage the use of imaging techniques that are appropriate in a given case. Since there is evidence of both over- and under-utilization of radiological procedures, further development and dissemination of practice guidelines seems promising. Linking reimbursement to such guidelines would further encourage adoption, as would

implementation through computerized physician order entry systems. One Massachusetts teaching hospital recently began to phase in a new evidence-based clinical system for diagnostic imaging. The system integrates multiple clinical databases to give physicians instant information for ordering appropriate imaging tests including outcomes data on thousands of similar patients. In the future, it will feature medical literature and best-practice guidelines for choosing the proper diagnostic imaging tests.

In the longer term, increased use of computerized medical records, especially those available through the Internet or local networks, may help to reduce utilization rates of diagnostic tests in general. Studies have found that 10% or more of diagnostic testing is due to retesting because test results were unavailable to the treating physician at the point of service. This could be largely eliminated by better access to patient information on a timely basis.¹²

As is true for pharmaceuticals, increased evidence of the value of certain tests to screen for common serious illnesses—electron-beam CT scans for coronary artery disease or low-dose spiral CT scans for lung cancer—could substantially increase costs in these areas in the next several years. While cost should not deter the emergence of truly valuable new technologies, attention must be paid to whether and how (and at what price) the emerging technology surpasses current technology. The extra cost of innovation must be proven to deliver value.

Endnotes

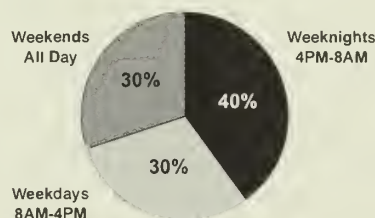
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Did you know?

Most ED Visits Occur when Other Options Are Not Available

The new DHCFC emergency department (ED) database includes data on patients treated in hospital EDs, but not admitted for an inpatient or observation stay. Analysis of these data shows that 70% of such ED patients arrived during evening and weekend hours, when most physicians' offices, clinics and health centers were closed. While many of these patients undoubtedly had emergencies, it is likely that some could have used more appropriate, less expensive settings had they been available.

Massachusetts ED Use by Day and Time, FY02



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